INTERNATIONAL STANDARD

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21549-1

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Health informatics — Patient healthcard data —

Part 1:
General structure

Informatique de santé — Données relatives aux cartes de santé des patients —

Partie 1: Structure générale

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 21549-1 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

This second edition cancels and replaces the first edition (ISO 21549-1:2004), which has undergone a minor revision. The following changes have been made.

— Foreword: the title of Part 7 was changed to "Medication data".

— Scope: the restriction "This part does not apply to multi-application cards" was deleted and other wording was improved.

— Normative references: ISO 21549, Parts 2 to 8, were added.

— Clause 5: the title of ISO 21549-7 was changed to "Medication data" in the text and in Figure 1, and references to ISO 21549, Parts 2 to 7, were reworded to shorten them.

ISO 21549 consists of the following parts, under the general title *Health informatics — Patient healthcard data*:

— *Part 1: General structure*

— *Part 2: Common objects*

— *Part 3: Limited clinical data*

— *Part 4: Extended clinical data*

— *Part 5: Identification data*

— *Part 6: Administrative data*

— *Part 7: Medication data*

— *Part 8: Links*

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 records, 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 Person" 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 relate), 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 and clinical data.

Device data are defined to include:

— identification of the device itself;

— 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:

— complementary person(s)-related data;

— identification of the funding of healthcare, 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);

— related actions planned, requested or performed.

Because a data card essentially provides specific answers to definite queries while at the same time there is 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.

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Data in the four categories above share many features. For instance, each may need to include ID numbers, names and dates. Some information may also have clinical as well as administrative uses. Therefore it has been considered inadequate to provide a simple list of items carried by healthcare data cards without applying a generic organization, based upon the existence of basic data elements. These may be defined by their characteristics (e.g. their format), and from them compound data objects may be constructed; several such objects may also share attributes.

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112b490fb627/iso-21549-1-2013

Health informatics — Patient healthcard data —

Part 1:
General structure

1 Scope

This part of ISO 21549 defines a general structure for the different types of data to be defined in other parts of ISO 21549 using UML notation. ISO 21549 defines data structures held on patient healthcards compliant with the physical dimensions of ID-1 cards, as defined by ISO/IEC 7810.

2 Normative references

The following referenced documents are indispensable for the application 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/IEC 7810, *Identification cards — Physical characteristics*

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

ISO 21549-3, *Health informatics — Patient healthcard data — Part 3: Limited clinical data*

ISO 21549-4, *Health informatics — Patient healthcard data — Part 4: Extended clinical data*

ISO 21549-5, *Health informatics — Patient healthcard data — Part 5: Identification data*

ISO 21549-6, *Health informatics — Patient healthcard data — Part 6: Administrative data*

ISO 21549-7, *Health informatics — Patient healthcard data — Part 7: Medication data*

ISO 21549-8, *Health informatics — Patient healthcard data — Part 8: Links*

3 Terms and definitions

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

3.1
data object
collection of data that has a natural grouping and may be identified as a complete entity

3.2
healthcare data card
card conformant to ISO 7816 (all parts) intended for use within the healthcare domain

3.3
patient healthcard
healthcare data card containing data related to a unique record person intended for use within the healthcare domain

Note 1 to entry: The term "patient" is not intended to determine that the record person is currently a subject of care.

3.4
record
collection of data

3.5
record person
individual about whom there is an identifiable record containing person-related data

4 Symbols and abbreviated terms

UML   Unified Modelling Language

5 Basic data object model for a healthcare data card — Patient healthcard data object structure

5.1 Overview

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.

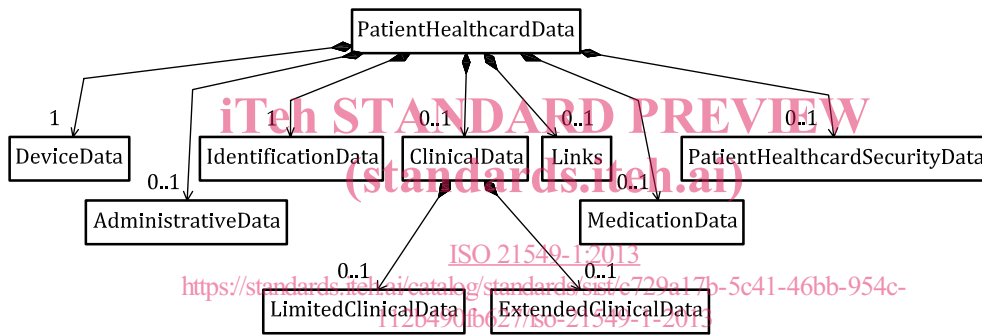The classes shown in Figure 1 are defined in ISO 21549, Parts 2 to 8.

Figure 1 — Patient healthcard data: Overall structure

The content of this object-oriented structure is described below and intrinsically will also require the use of data objects defined within other parts of ISO 21549.

NOTE   This part of ISO 21549 is purely applicable to patient healthcards containing health data. Data objects containing financial and healthcare reimbursement data are not defined within this part of ISO 21549.

5.2 Device data

This data object incorporates data specific to the device which is the patient data card itself. For instance, if the card is a "smart card", this data object incorporates the unique identifiers of the manufacturers, the chip manufacturers, the card personalizers and the unique identifier of the device itself, as well as other pertinent data. This data object is technology specific and, as such, falls outside the scope of this part of ISO 21549.

5.3 Identification data

This data object, as defined in ISO 21549-5, incorporates data that provide for the unique identification of the holder to whom the records relate.

NOTE   In some circumstances a "patient" data card may (in the case of a family insurance card) contain records related to more than one individual.

5.4 Administrative data

This data object, as defined in ISO 21549-6, incorporates data that provide for administration for healthcare in relation to which the records relate.

NOTE   In some circumstances a "patient" data card may (in the case of a family healthcare card) contain records related to more than one individual.

5.5 Clinical data

This data object, as defined in ISO 21549-3 and ISO 21549-4, incorporates data that are intended to aid the delivery of clinical care to which the records relate.

NOTE 1   In some circumstances a "patient" data card may (in the case of a family healthcare card) contain records related to more than one individual.

NOTE 2   According to ISO 21549-3, Clause 1, and ISO 21549-4, Clause 1, it is not possible to be conformant with this part of ISO 21549 and include data that are recorded expressly against the record-related individual's consent.

5.6 Links

This data object, as defined in ISO 21549-8, is intended to provide references and links to the record person to whom the record relates.

NOTE 1   In some circumstances a "patient" data card may (in the case of a family insurance or healthcare card) contain records related to more than one individual.

NOTE 2   It is intended that this object will contain data that provide for the same functionality as a community wide index. This object can contain URLs for records relating to the record person. Because of security limitations this does not mean that provision of the URL will automatically grant access to the data contained therein.

5.7 Medication data

This data object, as defined in ISO 21549-7, incorporates data equivalent to prescription information to which the records relate.

NOTE   In some circumstances a "patient" data card may (in the case of a family healthcare card) contain records related to more than one individual. However, with the structure as defined in Figure 1, it is only possible to have records related to one individual on the healthcard, which is as seen in current common usage.

5.8 Patient healthcard security data

This data object, as defined in ISO 21549-2, incorporates data objects which are able to store data that may be required for the provision of security functions.