INTERNATIONAL STANDARD

ISO 21549-1

First edition
2004-05-15

Health informatics — Patient healthcard data —

Part 1: General structure

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

Partie 1: Structure générale

Reference number
ISO 21549-1:2004(E)

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Published in Switzerland

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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*.

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: Electronic prescription (medication data)*
- *Part 8: Links*

At the time of publication of this part of ISO 21549, some of these parts were in preparation.

This work is being carried out by ISO/TC 215 in collaboration with CEN/TC 251, *Medical informatics*, under the Vienna Agreement, with ISO having the lead role. This new series of International Standards is intended to replace the European Prestandard ENV 12018 ratified by CEN in 1997.

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 data bases 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 into 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 and clinical data.

Device data is 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-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 person (HCP);
- related actions planned, requested or performed.

Because a data card essentially provides specific answers to definite queries, whilst at the same time there is a need to optimize the use of memory by avoiding redundancies, a “high-level” object-modelling technique (OMT) has been applied with respect to the definition of healthcare data card data structures.

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.

Health informatics — Patient healthcard data —

Part 1:
General structure

1 Scope

This part of ISO 21549 is Part 1 of a multi-part standard that defines data structures held on patient healthcards compliant with the physical dimensions of ID-1 cards as defined by ISO/IEC 7810. This part of ISO 21549 does not apply to multiapplication cards. It defines a general structure for the different types of data defined in the other parts of the standard using UML notation.

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*

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
machine-readable card, conformant to ISO/IEC 7810, 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 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 has 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 card.

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

The classes shown in Figure 1 are defined within the other parts of this International Standard (see the Foreword).

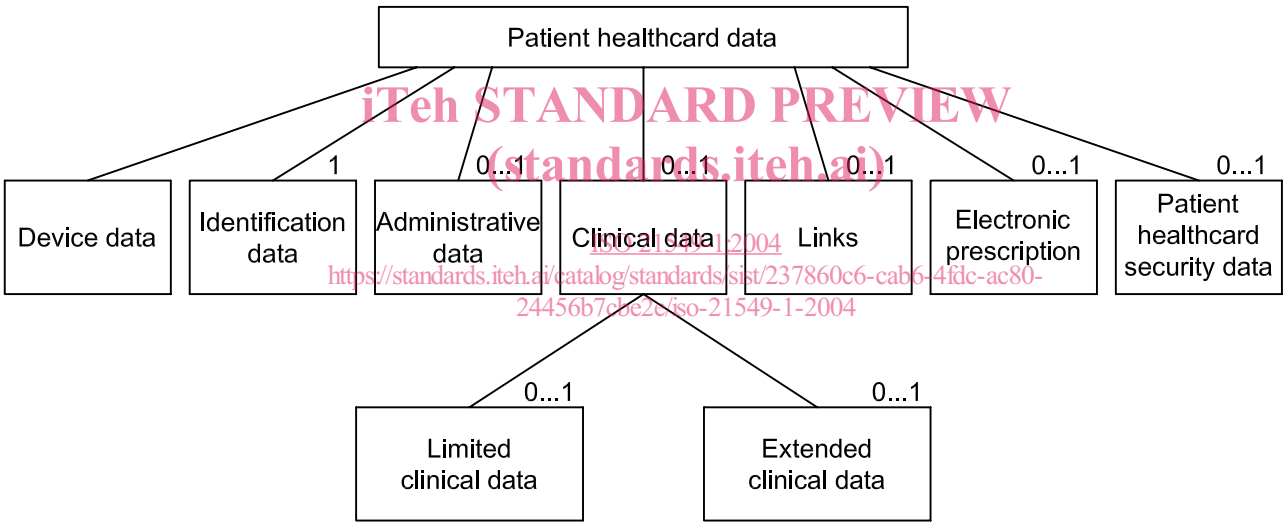

Figure 1 — Patient healthcard data — Overall structure

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 solely applicable to patient healthcards containing health data. Data objects containing financial and healthcare reimbursement data are not defined in this International Standard.

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 unique identifiers of the card manufacturer, the chip manufacturer, the card holder and 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 Part 5 of this International Standard, incorporates data that provides for the unique identification of the individual 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 Part 6 of this International Standard (in preparation), incorporates data that provides for administration for healthcare 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 Part 3 and Part 4 of this International Standard, incorporates data that is intended to aid the delivery of clinical care 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.

Healthcards containing data that are recorded expressly against the consent of the individual to whom the records relate are not conformant with this International Standard.

5.6 Links

This data object, as defined in Part 8 of this International Standard (in preparation), is intended to provide references and links to the individual to whom 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 It is intended that this object will contain data that provides 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 Electronic prescription (medication data)

This data object, as defined in Part 7 of this International Standard, 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 defined in Figure 1, it is only possible to have records related to one individual on the healthcard, which is current common usage.

5.8 Patient healthcard security data

This data object, as defined in Part 2 of this International Standard, incorporates data objects which are able to store data that may be required for the provision of security functions.