INTERNATIONAL STANDARD

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Health informatics — Patient healthcard data —

Part 3: Limited clinical data

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

Partie 3: Données cliniques limitées

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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 21549-3 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.

This part of ISO 21549 describes and defines the limited clinical data objects used in or referenced by patient-held health data cards using UML, plain text and abstract syntax notation (ASN.1).

It does not describe or define the common objects defined within part 2 of this International Standard, even though they are referenced and utilized within this document.

Health informatics — Patient healthcard data —

Part 3: Limited clinical data

1 Scope

This part of ISO 21549 describes and defines the limited clinical data objects used in or referenced by patient-held health data cards using UML, plain text and abstract syntax notation (ASN.1).

It is applicable to situations in which such data are recorded on or transported by patient healthcards whose physical dimensions are compliant with those of ID-1 cards as defined by ISO/IEC 7810.

This part of ISO 21549 specifies the basic structure of the data contained within the data object limited clinical data, but does not specify or mandate particular data-sets for storage on devices. In particular, the data contained within the data objects in limited clinical data are intended to aid the delivery of emergency care, but are by themselves neither intended, nor suitable, for the provision of all the information required.

The detailed functions and mechanisms of the following services are not within the scope of this part of ISO 21549 (although its structures can accommodate suitable data objects specified elsewhere):

— the encoding of free text data;

— security functions and related services which are likely to be specified by users for data cards, depending on their specific application, for example confidentiality protection, data integrity protection, and authentication of persons and devices related to these functions;

— access control services which may depend on active use of some data card classes such as microprocessor cards;

— the initialization and issuing process (which begins the operating lifetime of an individual data card, and by which the data card is prepared for the data to be subsequently communicated to it in accordance with this part of ISO 21549).

The following topics are therefore beyond the scope of this part of ISO 21549:

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

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

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

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 3166-1, *Codes for the representation of names of countries and their subdivisions — Part 1: Country codes*

ISO 7498-2:1989, *Information processing systems — Open systems interconnection — Basis reference model — Part 2: Security architecture*

ISO/IEC 7810, *Identification cards — Physical characteristics*

ISO 21549-2:2004, *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.

3.1
confidentiality
the property that information is not made available or disclosed to unauthorized individuals, entities or processes

[ISO 7498-2:1989]

3.2
data integrity
the property that data have not been altered or destroyed in an unauthorized manner

[ISO 7498-2:1989]

3.3
data object
collection of data that has a natural grouping and may be identified as a complete entity

3.4
data origin authentication
corroboration that the source of data received is as claimed

[ISO 7498-2:1989]

3.5
healthcard holder
individual transporting a healthcare data card which contains a record with the individual identified as the major record person

3.6
healthcare data card
machine-readable card, conformant to ISO 7810, intended for use within the healthcare domain

3.7
linkage
ability to join together two or more entities or parts

NOTE It may be physical, electrical or relational.

3.8
record
collection of data

3.9
record person
individual about whom there is an identifiable record containing person-related data

3.10
security
combination of confidentiality, integrity and availability

4 Symbols and abbreviated terms

ASN.1 Abstract syntax notation, version 1

EN European Standard

HCP Healthcare person

IEC International Electrotechnical Commission

ISO International Organization for Standardization

UML Unified modelling language

UTC Coordinated universal time

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

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 below in Figure 1.

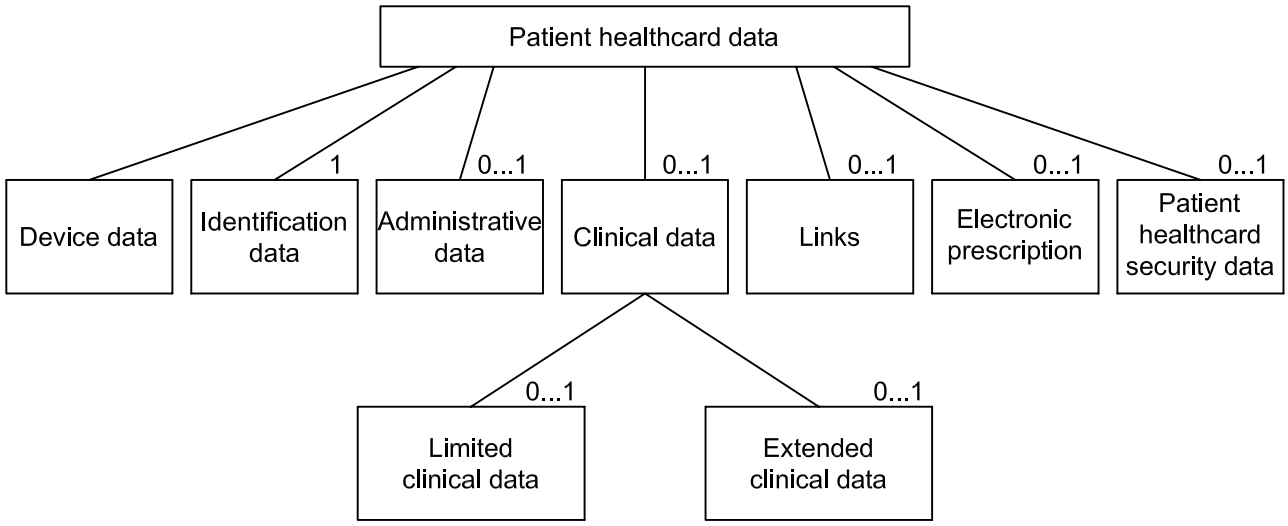

Figure 1 — Patient healthcard data — Overall structure