SLOVENSKI STANDARD
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Nadomeġļ a:
SIST ENV 12538:2003
SIST ENV 12539:2003
SIST ENV 1613:2003

Zdravstvena informatika ï Sporoļ ila z zahtevami in poroļ ili za (diagnostiļ no) storitev ï 1. del: Osnovne storitve, ki vkljuļ ujejo napotitev in odpustitev (pacientov)

Health informatics - Service request and report messages - Part 1: Basic services including referral and discharge

Medizinische Informatik - Serviceabfragen und Berichtsnachrichten - Teil 1: Grundsätzliche Dienstleistungen inklusive ärztliche Überweisung und Entlassung

Informatique de santé - Messages de demande et de compte-rendu de prestation de santé - Partie 1 : Prestations de base y compris adressage et fin de prise en charge

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ICS:

35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology

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Health informatics - Service request and report messages - Part 1: Basic services including referral and discharge

Informatique de santé - Messages de demande et de compte-rendu de prestation de santé - Partie 1 : Prestations de base y compris adressage et fin de prise en charge

Medizinische Informatik - Serviceabfragen und Berichtsnachrichten - Teil 1: Grundsätzliche Dienstleistungen inklusive ärztliche Überweisung und Entlassung

This European Standard was approved by CEN on 14 February 2005.

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Foreword

This document (EN 14720-1:2005) has been prepared by Technical Committee CEN/TC 251 “Health informatics”, the secretariat of which is held by SIS.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2005, and conflicting national standards shall be withdrawn at the latest by September 2005.

This document has been prepared under mandate M/255 given by the European Commission and the European Free Trade Association.

This document supersedes ENV 1613:1995, ENV 12538:1997 and ENV 12539:1997.

This document includes a Bibliography.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Introduction

The use of data processing and telecommunications capabilities have made possible the interchange of information in machine-readable and machine processable formats. The Information Technology and Data Management environment consists of a variety of computer systems with numerous hardware and operating system platforms. Application programs span a wide range of qualities of design and support. Interoperability – the ability of software and hardware on multiple machines from multiple vendors, to communicate – is the key to automated interchange of information in healthcare. As interoperability [3.39] increases, it is essential to provide appropriate information interchange standards [3.49].

Computer systems are in use for the storage and processing of information in many healthcare service departments and clinical laboratories. This document provides a set of message types [3.42] that enable the electronic transfer of messages in the healthcare services domain.

This document supersedes ENV 12539 (*Medical informatics - Request and report messages for medical service departments*), ENV 12538 (*Medical informatics - Referral and discharge messages*) and ENV 1613 (*Medical informatics - Messages for exchange of laboratory information*).

A combination of the following factors provide the motivation for this document:

— Standards are required to facilitate electronic transfer of healthcare services [3.27] related messages and reports between the many systems currently used.

— Implementation of the messages specified by this document will enable the transmission of general messages for electronic interchange between computer systems used by healthcare parties [3.25] in the healthcare service domain.

— Electronic transfer of these healthcare service related messages and reports reduces the need for manual entry and the risk of transcription errors. It also results in greater efficiency leading to more efficient and economic healthcare provision.

— This document imposes EDI messages in the domain of healthcare services to be defined in a way that ensures all necessary data is made available, thus significantly reducing the risk of misinterpretation of request and report related messages. This document includes the hierarchical and linear message descriptions, together with coding tables, where appropriate.

This document has been developed following the methods recommended in the CEN Report on "Medical Informatics - Methodology for the development of healthcare messages" (CR 12587:1996). However, in accordance with the decisions of CEN/TC 251, a different modelling technique has been used in compiling this revised standard. A subset of the Unified Modelling Language (UML) has been used, as described in Annex C.

This document takes account of message information model development being undertaken by HL 7 version 3 and aligns with HL7 v3 RIM version 1.20. HL7 is designated as an ANSI Accredited Standards Development Organisation.

This document specifies messages in a syntax [3.53] independent form. Its requirements for conformance define the structure for these messages. Compliant messages can be developed in a variety of implementation syntaxes and these syntax specific implementations may be the subject of future standards.

This document is directly relevant to suppliers of computer systems for use in systems development. Its provisions are also relevant to those planning, specifying, procuring or implementing information systems for use in clinical laboratories, hospitals, general practices, clinical departments and specialist clinics.

1 Scope

1.1 The scope of the messages specified by this document comprises healthcare service requests and reports related to laboratory and diagnostic investigations [3.28] as well as specialist services [3.35] carried out by healthcare service providers on subjects of care [3.51]. They cover electronic information exchange between computer systems used by healthcare parties requesting the services of, healthcare service providers.

1.2 This document is applicable to messages requesting healthcare services or reporting results of healthcare services independent of medical specialty. The messages can be used for:

— laboratory services, such as clinical biochemistry, clinical microbiology and haematology;

— diagnostic services, such as radiology, anatomical pathology and nuclear medicine;

— specialist services, such as referral and discharge messages.

1.3 This document does not specify the manner in which healthcare services are divided between specialties as this varies in accordance with national and local practices.

1.4 This document is applicable to requests for new investigation or specialist service and also modifications of previously issued requests.

1.5 It is applicable both to the subject of investigation as well as samples that are obtained from subjects of investigation at the point of care or at any other location and submitted to the healthcare services, and to requests for investigation for which the healthcare service is requested to obtain samples. The subject of investigation can be a person, an animal, a group of animals or a material.

1.6 The messages support standing orders for healthcare services.

1.7 This document is applicable to new reports and modifications of previously issued reports.

1.8 The messages it specifies support the communication of partial, supplementary, complete and cumulative reports. Reporting modes which may be implemented using this document include:

— sending a requested healthcare service report only when all results are available;

— sending individual results as they become available;

— sending new results as part of a cumulative report;

— sending partial results.

1.9 The results may include numeric values, ranges, ratios, coded information, free text as well as large binary objects (multimedia objects).

1.10 This document is not applicable to prescribing, dispensing and administration of medication or ordering blood transfusion products. The EN is however, applicable for requesting and reporting of investigations in connection with blood transfusions.

1.11 This document has not been developed to meet the needs of messages supporting administration, financing, management, interpersonal mail or external quality control, nor of messages communicating sample collection lists, work lists or queries.

1.12 This document does not support negative acknowledgement or error indication at the application level, nor positive acknowledgment or cancellation messages at the application level.

1.13 The provisions of this document have been validated in the domains and for the purposes described above (see 1.1 and 1.2). However messages conforming to this EN may be considered by some user communities

to be suitable for their needs for purposes outside this Scope. Use of the messages in such circumstances is not precluded by the Scope.

1.14 Two groups of messages have been identified within Scope:

Group 1: Basic healthcare service request messages including referral messages;

Group 2: Basic healthcare service report messages including discharge messages.

1.15 These groups of messages support communication between healthcare parties [3.25]. The healthcare party may be a person (such as a doctor or other healthcare professional [3.26]) or a healthcare organisation [3.24] (such as a hospital, clinic or department).

1.16 A basic healthcare service request message is sent from a healthcare party in the role as healthcare service requester to another healthcare party in the role of healthcare service provider as well as to other involved parties (copy destinations).

1.17 A basic healthcare service report message is sent from a healthcare party in the role as healthcare service provider to another healthcare party in the role as healthcare service requester and/or other involved healthcare parties (copy destinations).

1.18 Messages for transmission of requests for healthcare services from a healthcare service provider, covered by the scope of this document, should enable electronic interchange of the semantic content defined in the hierarchical message descriptions (HMD) [3.36] for healthcare service request messages in Clause 6.

1.19 Messages for transmission of Reports from a healthcare service provider, covered by the scope of this document, should enable electronic interchange of the semantic content defined in the HMDs for healthcare service reports messages in Clause 6.

1.20 Implementable message specifications (IMS) [3.37] should conform to the HMDs defined in this document. Defined messages or message subsets should support as a minimum all mandatory objects and attributes defined in the HMD of this document. They should also support the relationships between all referenced objects as defined by the HMD.

1.21 IMS should be expressed in terms of a syntax that is an International Standard except where the healthcare user requirements cannot be met by using such a standard syntax.

1.22 When implementing information exchange based upon this document, data protection and confidentiality [3.13] principles have to be guaranteed according to the laws and codes of professional practice actually in force in the actual CEN member country. The mechanisms needed to secure data integrity [3.14], data protection and confidentiality, authentication [3.4] of communicating parties and subjects of investigation are outside the scope of this document. Guidance can be found in ISO/TR 18307.

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.

CEN/TS 14796:2004, *Health informatics – Data types*

prEN 14822-1, *Health informatics – General purpose information components – Part 1: Overview*

prEN 14822-2, *Health informatics – General purpose information components – Part 2: Non-clinical*

prEN 14822-3, *Health informatics – General purpose information components – Part 3: Clinical*

prCEN/TS 14822-4, *Health informatics – General purpose information components – Part 4: Message headers*

3 Terms and definitions

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

3.1
analysable object
object derived from or to be derived from a subject of investigation as part of a healthcare service investigation

NOTE Analysed object is a generalisation that includes samples taken from a subject of investigation and physical or digital records of information derived from a subject of investigation as part of a healthcare service. An analysed object that is not a sample is referred to as a study product.

EXAMPLE 1 An X-ray image, a series of X-ray images, part of an X-ray image. The image may exist in a digitised form or as a film.

EXAMPLE 2 An electrocardiograph (ECG) monitor tracing or a twelve lead ECG.

EXAMPLE 3 An organ removed during surgery or post-mortem, a biopsy, a particular slide containing a section taken from a biopsy.

EXAMPLE 4 A view observed through an endoscope, an observation during an echocardiographic examination.

3.2
application
identifiable computer running a software process

3.3
attribute
a characteristic of an object or entity

[ENV 13730-1:2001]

3.4
authentication
the process of reliably identifying security subjects by securely associating an identifier and its authenticator

[ISO 7498-2:1989]

3.5
authorisation
the granting of rights, which includes granting of access based on access rights

[ISO 10181-2:1996]

3.6
care service recipient
person, animal or animal group that is the primary focus of one or more care services

NOTE This may be different from the subject of investigation.

3.7
clinical information
information about a subject of care, relevant to the health or treatment of that subject of care, that is recorded by or on behalf of a healthcare professional

[ENV 1613:1995]

NOTE 1 Clinical data/information is related to the health and healthcare of an individual collected from or about an individual receiving healthcare services. Includes a caregiver's objective measurement or subjective evaluation of a patient's physical or mental state of health; descriptions of an individual's health history and family health history; diagnostic studies; decision rationale; descriptions of procedures performed; findings; therapeutic interventions; medication prescribed; description of

responses to treatment; prognostic statements; and descriptions of socio-economic and environmental factors related to the patient's health. [ASTM E1769, CPRI]

NOTE 2 Clinical information about a subject of care may include information about the subject of care's environment or about related people where this is relevant.

3.8
clinical investigation
laboratory, physiological, radiological or other healthcare examination that leads to the production of one or more results

3.9
clinical observation
clinical information excluding information about treatment and intervention

NOTE Clinical information that does not record an intervention is by nature a clinical observation. The observer may be the patient or related person (information about symptoms, family history, occupation or life style), or a healthcare professional (information about physical signs, measurements, properties observed or diagnoses). While information about the nature of a planned or performed treatment is excluded by the definition, clinical observations may be recorded as the results of a treatment or during the course of a treatment or as its result.

3.10
code meaning
element within a coded set

EXAMPLE "Paris Charles-De-Gaulle" which is mapped on to the three-letter abbreviation "CDG" by the coding scheme for three-letter abbreviations of airport names.

[EN 1068:1993]

3.11
code value
result of applying a coding scheme to a code meaning

EXAMPLE "CDG" as the representation of "Paris Charles-De-Gaulle" in the coding scheme for three-letter representations of airport names.

[EN 1068:1993]

3.12
coding scheme
collection of rules that maps the elements of one set on to the elements of a second set

[EN 1068:1993]

3.13
confidentiality
the property that information is not made available or disclosed to unauthorised individuals, entities or processes

[ISO 7498-2:1989]

3.14
data integrity
the property that data or a message's content has not been altered or destroyed in an unauthorised manner

NOTE 1 In order to achieve this requirement for the data, the integrity of all systems should be preserved including hardware, system design, software design, implementation and maintenance.

NOTE 2 This definition includes both accidental and intentional events and actions.

[ISO 7498-2:1989]

3.15
discharge message
report from a specialist service provider concerning performed and/or planned treatment/examinations

NOTE Discharge summary letter is one type of a discharge message.

3.16
domain information model (DIM)
conceptual model describing common concepts and their relationships for communication parties required to facilitate exchange of information between these parties within a specific domain of healthcare

[CR 12587:1996]

3.17
electronic healthcare record (EHCR)
healthcare record concerning the subject of care in computer readable form

[ENV 13606-1:2000]

3.18
general message description (GMD)
subset of a domain information model [3.16] prescribing the information content and semantic structure of a message used to meet one or more identified information interchange requirements

NOTE General message descriptions are independent of the syntax used for constructing an actual message. They provide statement of the information interchange requirements in a form that can be implemented using different syntaxes.

[CR 12587:1996][ENV 1613:1995]

3.19
health informatics
scientific discipline that is concerned with the cognitive, information processing and communication tasks of healthcare practice, education and research, including the information science and technology to support these tasks

[Directory of the European Standardisation Requirements for Healthcare Informatics and Telematics v.2.2, 1994]

3.20
healthcare
provision of health related services

NOTE 1 This includes more than performing procedures on subjects of care. It includes also e.g. the management of information about patients, their health status and their relationship with their healthcare framework.

[ENV 13940:2001]

NOTE 2 Includes any: 1) preventative, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, counselling, service, or procedure with respect to the physical or mental condition, or functional status, of a patient or affecting the structure or function of the body; 2) sale or dispensing of a drug, device, equipment, or other item pursuant to a prescription; or 3) procurement or banking of blood, sperm, organs, or any other tissue for administration to patients. [HIPAA]

3.21
healthcare agent
healthcare person, healthcare organisation, healthcare device or healthcare software component that performs a particular role in a healthcare activity

[prENV 12265:1995, modified]

3.22
healthcare administrative information
information about a subject that is requested or required by a healthcare party to enable, finance or manage the provision of healthcare services to that subject

3.23
healthcare coding scheme designator
unique permanent identifier of a healthcare coding scheme registered for use in information interchange under the terms of ENV 1068

3.24
healthcare organisation
organisation involved in the direct or indirect provision of healthcare services

NOTE 1 Groupings or subdivisions of an organisation, such as departments or sub-departments, may also be considered as organisations where there is need to identify them.

NOTE 2 Healthcare organisations is a subset of healthcare agents.

[prEN 14822-2:2003]

3.25
healthcare party
organisation or person involved in the direct or indirect provision of healthcare services to an individual or to a population

NOTE Healthcare parties are a subset of healthcare agents.

[prEN 14822-2:2003]

3.26
healthcare professional
person involved in the direct or indirect provision of healthcare services to an individual or to a population

[prEN 14822-2:2003]

NOTE The types of registering or accrediting bodies differ in different countries and for different professions. Nationally recognised bodies include local or regional governmental agencies, independent professional associations and other formally and nationally recognised organisations. They may be exclusive or non-exclusive in their territory.

EXAMPLES Physicians, registered nurses and pharmacists.

3.27
healthcare service
service provided with the intention of directly or indirectly improving the health of the people, or populations to whom it is provided

[ENV 1613:1995]

3.28
healthcare service investigation
healthcare service investigation that is, or may be requested or reported using a message specified in accordance with this document

NOTE 1 A healthcare service investigation may be indicated by the terms the requester uses when making a request, or by terms used by the healthcare service provider to refer to an investigation or to actions undertaken while performing an investigation.

NOTE 2 A healthcare service investigation may be subdivided into several separate investigations. Each constituent investigation is also considered as a healthcare service investigation (e.g. examination of a biopsy may include macroscopic