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Health informatics - Electronic healthcare record communication - Part 4: Messages for the exchange of information

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Health informatics - Electronic healthcare record communication - Part 4: Messages for the exchange of information

This European Prestandard (ENV) was approved by CEN on 29 July 1999 as a prospective standard for provisional application.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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FOREWORD

This European Prestandard has been prepared by Technical Committee CEN/TC 251 "Health informatics", the secretariat of which is held by SIS.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this European Prestandard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

This is Part 4 of a multipart standard on *Electronic Healthcare Record Communication*.

The multipart standard consists of the following parts:

- Part 1: Extended Architecture
- Part 2: Domain Term List
- Part 3: Distribution Rules
- Part 4: Messages for the Exchange of information

This Prestandard was drafted using the conventions of the ISO/IEC directive part 3.

All annexes of Part 4 are Informative.

INTRODUCTION

This European Prestandard provides a set of messages that enable the electronic transfer of healthcare record information between heterogeneous systems. These messages address the needs and capabilities of current healthcare record systems. They also take account of the more sophisticated requirements of future systems.

A combination of the following factors provide the motivation for this European Prestandard:

— Many hospitals, clinics and doctors now store the healthcare records of their patients in an electronic form.

Current electronic healthcare record systems are heterogeneous in nature. They store information in a variety of structures that differ in their levels of detail and sophistication. Some differences are idiosyncratic but others reflect variations in user requirements determined by organisational structures or clinical specialties.

— Timely availability of healthcare records is essential to the safe delivery of high quality healthcare.

Healthcare professionals need access to a patient's healthcare record to inform their decisions. If necessary information is not available, this leads to errors, delays or repetition of procedures. The end results of missing information include health risks, inconvenience for the patient and expense for the service provider.

— During their lifetime patients are cared for by more than one healthcare professional.

Patients may see a different healthcare profession when they move home, travel or require care out of the normal working hours of their usual physician. Patients may receive continuing care from a team of professionals or from a combination of specialists relevant.

— Timely availability of healthcare records requires communication between different healthcare professionals who care for the same patient.

Since the professionals involved will often have different electronic healthcare record systems, these communications usually involve paper reports or unstructured electronic exchanges. The relative inaccessibility of information received in these forms detracts from the quality, completeness and usability of the electronic healthcare record.

Implementation of the messages specified by this European Prestandard will:

a) facilitate the transfer of electronic healthcare records or parts of these records;

b) enable the communication of requests for transfer of electronic healthcare records;

c) reduce the need for human intervention to manually duplicate entries in different healthcare record systems;

d) minimise the time and effort required for the introduction of information interchange agreements that support the exchange of electronic healthcare record information;

e) reduce the development effort required by suppliers to allow their systems to communicate with a wide range of other electronic healthcare record systems;

f) reduce the cost of information interchange between clinical information systems.

When implementing information exchange based on this European Prestandard, data security services, including confidentiality provisions, will need to comply with the laws in force in the different CEN member countries. Other European Prestandards currently under development address technical issues relating to meeting this need.

This European Prestandard 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 accord with the decisions of CEN TC251 WGI, a different modelling technique has been used. This is a subset of the Unified Modelling Language (UML) as documented in Annex A.

This European Prestandard specifies messages in a syntax independent form. Its requirements for conformance define the minimum acceptable content and 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 European Prestandard is directly relevant to suppliers of computer systems for use in hospitals, general practices, clinical departments and specialist clinics. Its provisions are also relevant to those planning, specifying, procuring or implementing information systems for use in departments, hospitals, general practices, clinical departments and specialist clinics.

1. Scope

This European Prestandard specifies messages that enable exchange of electronic healthcare record information between healthcare parties responsible for the provision of clinical care to an individual patient. These messages allow information from an electronic healthcare record held by one health professional to be sent to another health professional.

The messages specified by this European Prestandard can be used to convey:

- a complete copy of a patient's record as stored in one information system;
- parts of a patient's record that form a logically sound extract or summary of that record;
- parts of a patient's record used for updating a parallel record on another system.

The primary purpose of these messages is to support the provision of care to individual patients. The availability of consistent, continuing clinical care, when and where it is needed, requires appropriate and unambiguous communication between clinical professionals. The messages specified by this European Prestandard are designed to meet this requirement by enabling users of different clinical information systems to exchange electronic healthcare record information. Implementation of these messages will therefore assist the maintenance of timely and appropriate patient records.

This European Prestandard considers two distinct properties of electronic health record communication.

a) Readability
   - Communication of information in a form that can be rendered human-readable by the receiving system. If the exchange of electronic healthcare record information is to support individual patient care, clinicians using the receiving system need to be able to read and understand the transferred information.

b) Processability
   - Communication of information that can be incorporated into a record held by the receiving system in a way that enables it to be processed and retrieved as an integral part of that record. The benefits of electronic healthcare records include retrieval and processing for decision support, audit and research. If these benefits are to be fully realised, systems need to be able to process received information in ways that, while recognising the source of that information, are otherwise consistent with the processing of locally recorded information.

The European Prestandard specifies messages that permit exchange of electronic health record information with different levels of structure. The least structured level is sufficient to enable any receiving system to render the information in a human-readable form. The more structured levels enable information to be transferred in a manner that facilitates subsequent retrieval and processing.

The ability of communicating systems to achieve a particular level of interoperability by using these messages depends on:

- the compatibility of the structures in which the systems store patient records;
- the mappability of different forms of representation used by those systems (e.g. languages, terminologies and coding schemes);
- the level of trust between the communicating parties.

These factors will therefore determine how the messages specified by this European Prestandard are used.

This European Prestandard takes account of the following issues related to the confidentiality, source and status of the transferred information.

- *Distribution* – The messages include provisions for conveying and referencing distribution rules in the form specified in Part 3 of this European Prestandard. These distribution rules are intended to govern subsequent distribution of information. These rules may be applied to the entire message or to individual components within the message. This European Prestandard does not mandate a particular mechanism for the enforcement of distribution rules.
- *Attribution* – The messages support communication of attribution details regarding the originator and time of origin of information. Attribution information, including digital signatures, may be applied to the entire message or to individual components within the message. This European Prestandard does not mandate a particular mechanism for secure verification of digital attribution information. However, the algorithm specified in ENV12388 may be used for this purpose subject to the agreement of the communicating parties.

— *Integration* – The messages support the communication of information in a way that allows receiving systems to distinguish new information from information that they have already received.

Specific security requirements and the mechanisms to be used to meet these requirements are outside the scope of this European Prestandard. Implementers of the messages specified by this European Prestandard should ensure that the security mechanisms used satisfy national and international legislation, user requirements and ethical guidance.

The messages specified by this European Prestandard are general in nature. They meet the requirements for transferring electronic healthcare record information in a manner appropriate to a wide-variety of situations covering all clinical professions and specialties. However, to maximise the processability of communicated information for particular purposes, a specific profile of the messages specified in this European Prestandard may be required. A profile may restrict the degrees of freedom inherent in the general message and may specify additional types of data item that can be used within a communicating community.

The messages described in this European Prestandard are based on the architectural principles stated in Part 1 of this European Prestandard. This does not preclude the use of this message for communications between systems that do not conform to Part 1. The message applies the architectural principles in a way that facilitates clinically safe communication even between systems with widely different record structures. However, the faithfulness of communication of the structural richness of an electronic record will be greater in the case of systems that comply with or are closely aligned with all parts of this European Prestandard.

The messages specified by this European Prestandard are primarily aimed at conveying character-based information between systems. The messages also provide for references to binary objects, which may form part of an EHCR. However, the European Prestandard does not specify the format of such binary objects, nor does it specify the methods by which they shall be communicated or made available to a receiving system.

Communication of EHCR information is often associated with specific requests for intervention by or advice from the recipient of this information. The response from the recipient of EHCR information may similarly be accompanied by a specific report that they have undertaken (or have accepted responsibility for undertaking) a requested service. The messages specified in this European Prestandard are not designed for communication of these requests or reports, as these are standardised by previous European Prestandards[1]. However, if such communications require the exchange of detailed EHCR information the messages or components defined in this European Prestandard may be used for that purpose. To facilitate this, the "EHCR extract" class specified in this European Prestandard may be used in place of the "Clinical Information" class in messages specified in previous European Prestandards for healthcare messages.

The messages specified by this European Prestandard are not designed for communication with intermittently connected devices such as patient data cards. However, due account has been taken of the relevant European Prestandard covering this domain (ENV12018).

These messages are not validated for the exchange of EHCR information for other purposes such as administration, resource allocation, research or quality monitoring.

[1] ENV1613 "Medical Informatics - Messages for exchange of laboratory information", ENV12538 "Medical Informatics - Messages for patient referral and discharge" and ENV 12539 "Medical Informatics - Request and report messages for diagnostic service departments".

2. Normative References

This European Prestandard incorporates by dated or undated references, provisions from other publications. These normative references are cited in the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments and revisions of any of these publications apply to this European Prestandard only when they are incorporated in it by amendment and revision. For undated references the latest edition of the publication referred to, applies.

ISO639:1988	Symbols for languages, geographical areas and authorities
ISO6523	Data interchange - Structure for the identification of organizations.
ISO2382-4:1987	Information processing - Vocabulary Part 4: Organisation of data
ISO5281:1977	Information interchange - Representation of human sexes
ISO/IEC 7826-1	Information technology – General structure for the interchange of code values – Part 1: Identification of coding schemes
ISO/IEC 7826-2	Information technology – General structure for the interchange of code values – Part 2: Registration of coding schemes
ISO8601: 1988	Data elements and interchange formats - Information interchange - Representation of dates and times
ENV 1613:1995	Medical informatics - Messages for exchange of laboratory information
ENV 1614:1995	Medical informatics - Structure for nomenclature, classification, and coding of properties in clinical laboratory sciences
ENV 12018:1997	Medical informatics - Identification, administrative and common clinical data structure for Intermittently Connected Devices used in healthcare (including machine readable cards)
ENV 12265	Medical informatics - Electronic healthcare record architecture
ENV 12381:1996	Medical informatics - Time standards for healthcare specific problems
ENV 12388:1996	Medical informatics - Algorithm for Digital Signature Services in Health Care
ENV 12435	Medical informatics - Expression of the results of measurements in health sciences
ENV 12537-1:1997	Medical informatics - Registration of information objects used for EDI in healthcare - Part 1: The Register
ENV 12537-2:1997	Medical informatics - Registration of information objects used for EDI in healthcare - Part 2: Procedures for the registration of information objects used for electronic data interchange (EDI) in healthcare
ENV 12538:1997	Medical informatics - Messages for patient referral and discharge
ENV 12539:1997	Medical informatics - Request and report messages for diagnostic service departments
CR 12587:1996	CEN Report: Medical informatics - Methodology for the development of healthcare messages
ENV 12612:1997	Medical informatics - Messages for the exchange of healthcare administrative information
ENV 13606-:2000	Electronic healthcare record communication – Extended architecture
ENV 13606-2:2000	Electronic healthcare record communication – Domain term list
ENV 13606-3:2000	Electronic healthcare record communication – Distribution rules
ENV 13607:2000	Health Informatics - Messages for The Exchange of Information on Medicine Prescriptions

3. Definitions

For the purpose of this European Prestandard, the following definitions apply:

3.1.
annotation identifier

a means to summarise the key contextual information pertaining to a component complex or a data item.

NOTE the annotations are added to the record component as a coded value. The *component annotation* measure within Part 2 provides a means to summarise in a standardised form the key contextual information pertaining to an elementary or compounded entry, primarily to assist in its safe interpretation. A secondary purpose is to facilitate the retrieval of relevant entries by computerised searches. See Part 2 for more details.

3.2.
attestation

a binding of the healthcare agent (with digital signature) to a unit of information content to confirm the acceptance of the content.

3.3.
clinical information

information about a patient, relevant to the health or treatment of that patient, that is recorded by or on behalf of a healthcare professional.

NOTE Clinical information about a patient may include information about the patient's environment or about related people where this is relevant.

3.4.
cluster

original component complex used to aggregate data items and/or other clusters to represent a compound concept.

EXAMPLES A blood pressure measurement consisting of systolic and diastolic pressure, a collection or closely related clinical findings, results of a battery of laboratory investigations, a treatment schedule consisting of several individually specified preparations or dosages.

3.5.
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.

3.6.
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.

3.7.
coding scheme

collection of rules that maps the elements of one set on to the elements of a second set.

3.8.
communicating community

geographically or organisationally defined grouping of healthcare parties that agree to communicate, subject to an agreed set of constraints or guidelines.

3.9.
component name

attribute that is used to provide a title or label to an instance of an EHCR message component.

3.10.
component name category

attribute that provides a high level indication of the general nature of the content of a record component.

NOTE 1 These categories are assigned by or derived from the EHCR, depending upon the nature of the data or the process being carried out.

NOTE 2 See Part 2 for permissible values for different types of record component.

3.11.
composition

original component complex that contains a set of record components relating to one time and place of care delivery, a single session of recording or a single document included in the EHCR.

EXAMPLES Consultation note, operation note, discharge summary, vital signs chart, laboratory report.

3.12.
data item

single unit of data that in a certain context is considered indivisible.

NOTE 1 The content of data is dependent upon the structure and type of the identified data type.

NOTE 2 The context may mean that this component's content may represent for example either a single clinical statement (see Part 2) or a single complex type such as an X-ray report. Its granularity is determined by the context.

3.13.
digital signature

data appended to, or a cryptographic transformation of, a data unit that allows a recipient of a data unit to prove the source and integrity of the unit and protect against forgery e.g. by the recipient.

[ISO 7498-2]

3.14.
distribution rule

logical concept or rule intended to convey and govern distribution.

NOTE The form of representation of EHCR distribution rules is the subject of Part 3 of this Prestandard.

3.15.
distribution rule reference

attribute referencing a distribution rule.

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.

3.17.
electronic healthcare record
EHCR

healthcare record in computer readable form.

3.18.
electronic healthcare record architecture

a set of principles governing the logical structure and behaviour of electronic healthcare records that enables communication of the whole or part of a healthcare record.

3.19.
EHCR destination

communicating party that is the destination or intended of EHCR information that is requested, transferred or acknowledged in an EHCR message.

3.20.
EHCR extract

EHCR message component representing the entirety of a patient's electronic healthcare record or that part of the record contained within a particular instance of an EHCR message.

3.21.
EHCR source

communicating party that is the source or intended source of EHCR information that is requested, transferred or acknowledged in an EHCR message.

3.22.
EHCR message

generalisation applicable to all messages specified by this Prestandard for the purposes of requesting or providing EHCR information or for notifying another communicating party about this process.

3.23.
EHCR message component

part of an electronic healthcare record contained within an EHCR message in a form that renders it identifiable for the purposes of referencing and revision.

NOTE This European Prestandard specifies two types of EHCR message component. These are the "EHCR extract" and the "record component".

3.24.
EHCR message related agent

communicating party other than the source, intended source, destination or intended destination of EHCR information.

EXAMPLES Intermediary, forwarding agent, copy destination, trusted third party authenticating a request or provide EHCR message.

3.25.
EHCR notification message

message specified by this Prestandard for the purpose of conveying notifications about the sending, receipt, rejection or acceptance of a *request EHCR message* or *provide EHCR messages*.

3.26.
EHCR source
communicating party that is the source or intended source of EHCR information that is requested, transferred or acknowledged in an EHCR message.

3.27.
EHCR system

system for recording, retrieving and manipulating information in electronic healthcare records.

3.28.
folder

original component complex used to group record components collected and/or recorded during several contacts with a patient.

NOTE A folder may include information collected and recorded at different times and by different people.

3.29.
general message description
GMD

subset of a domain information model 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.

3.30.
headed section

original component complex representing a sub-division within a composition, the contents of which have a common theme or are derived through the same healthcare process.

3.31.
healthcare agent

healthcare person, healthcare organisation, healthcare device or healthcare software component that performs a role in a healthcare activity.

3.32.
healthcare agent function

reference to a healthcare agent that identifies them *only* in terms of their function in relation to another healthcare agent and not by an individual name or identifier.

NOTE The healthcare agent function allows a record component or message to refer to healthcare agents who are not individually identified at the time of recording.

EXAMPLE To send a message to the "duty doctor" in an emergency department, to indicate the contact details for a specialist's secretary, to distinguish between the parts of a pre-operative assessment applicable to the "anaesthetist".

3.33.
healthcare agent in context

one or more healthcare agents related together in a specified manner for the purposes of performing a particular role in a healthcare activity.

3.34.
healthcare agent in context reference

reference which uniquely identifies a healthcare agent in context.

NOTE: Use of a healthcare agent in context reference depends on the existence of shared information describing the healthcare agent in context to which it refers.

3.35.
healthcare agent role

role played by a healthcare agent (or by a healthcare agent in context) in a healthcare activity.

EXAMPLES Originator or author of a record entry, requester of a service, provider of a service, sender of a message, recipient of a message, person signing a message or record entry.

3.36.
healthcare agent relationship

relationship between two healthcare agents.

NOTE 1 A healthcare agent relationship may apply for a specified period of time.

EXAMPLE 1 Employee / employer

NOTE 2 A healthcare agent relationship may be specific to a particular healthcare agent role.

EXAMPLE 2 On behalf of / responsible for.

3.37.
healthcare device

device or equipment involved in the direct or indirect provision of healthcare services to an individual or to a population.

EXAMPLE ECG machine, auto-analyser, syringe pump.