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Health informatics - Blood transfusion related messages - Part 1: Subject of care related messages

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Health informatics - Blood transfusion related messages - Part 1: Subject of care related messages

This European Prestandard (ENV) was approved by CEN on 19 October 2000 as a prospective standard for provisional application.

The period of validity of this ENV is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the ENV can be converted into a European Standard.

CEN members are required to announce the existence of this ENV in the same way as for an EN and to make the ENV available promptly at national level in an appropriate form. It is permissible to keep conflicting national standards in force (in parallel to the ENV) until the final decision about the possible conversion of the ENV into an EN is reached.

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Foreword

This European Prestandard has been prepared by CEN/TC251 Health Informatics under mandate by the European Commission and the European Free Trade Association and under the supervision of WG1 & of CEN TC/251, the Technical Committee for Health Informatics. The Project Team members are experts from various European countries, including representatives from:

France (Team Leader), Austria, Germany, Sweden and UK.

This European Prestandard complies with the third edition of ISO/IEC Directives, part 3, 1997.

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.

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 increases, it is essential to provide appropriate information interchange standards.

This European Prestandard provides a set of messages that enable the electronic transfer of messages in the Blood transfusion domain.

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

Electronic messages developed in the Healthcare Informatics domain contain sensitive healthcare information about specified individuals that requires a high level of confidence both in the parties sending and receiving messages and that the information being made available is unchanged. Standards are required to facilitate electronic transfer of Blood Transfusion related messages and reports between the many systems currently used. Information transferred in the Blood Transfusion related messages and any reports passing between healthcare parties form part of the information system of each of the communicating parties. Electronic transfer of these Blood transfusion related messages and reports reduces the need for manual entry and the risk of transcription errors. It also results in greater efficiency leading to better healthcare provision.

This Prestandard requires EDI messages in the domain of Blood transfusion to be defined in a way that significantly reduces the risk of misinterpretation of issued blood transfusion related messages. Deliverables are included that are usable by software implementers and health professionals working in the field of Blood transfusion. This report includes the hierarchical and linear message descriptions, together with coding tables, where appropriate. The outputs of this work may also be used in the domain of tissue and organ transplantation.

Implementation of the messages specified by this European Prestandard will enable the transmission of general messages for electronic interchange between computer systems used by healthcare parties in the Blood transfusion domain.

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 development. Its provisions are also relevant to those planning, specifying, procuring or implementing information systems for use in the Blood transfusion domain.

prENV 13730-1

Health Informatics - Blood Transfusion Related Messages
Part 1: Subject of Care Related Messages

1 Scope

Transfusion of blood [**3.10**] and Blood components[**3.11**] to subjects of care[**3.51**] is a medical activity that is subject to many legal regulations and constraints. Many problems may be encountered during treatment due to immunological conditions, transmitted diseases, sustainability and other difficulties. Mistakes and failures may have serious or even fatal consequences. Minimising human activity through the increased use of data processing and automated messaging will introduce an additional safety mechanism.

This European Prestandard (prENV) specifies general messages[**3.43**] for electronic information interchange between computer systems used by healthcare [**3.30**] parties in the Blood transfusion [**3.17**] domain. The content and structure of the messages specified in this prENV have been developed with the aim of optimising the safety of Blood transfusion activity and to facilitate compliance monitoring and secure audit trails [**3.4**].

This European Prestandard is applicable to Blood transfusion related messages including those for:

- the collection of blood from donor
- preparation of Blood components
- classification of Blood donations
- dispensing of Blood components (to be transfused) to the recipient

Within the blood transfusion process there are a number of actors:

(1) The *Blood component User*, generally a member of a care unit, is the customer of a Blood component dispenser. He establishes the need for transfusion and makes a request to the blood transfusion service. Depending on the internal organisation [**3.45**] of the healthcare organisation, a request may be made for preparatory investigations, such as serological tests, prior to the transfusion.

The Blood component User [**3.15**]:
receives reports of blood group analysis;
accomplishes the transfusion;
reports back any delay in the activity;
reports the outcome of any eventual complications.

The requesting party and the transfusing party can physically be two different healthcare professionals, but are illustrated as instances of one generic actor, the Blood component user.

(2) The Blood component *Dispenser* [**3.12**] obtains Blood components from one or more providers, then stores and dispenses them to the user. This actor may appear as a separate entity, or as subdivision, within either the class producer or user. In certain circumstances communication may be required with a different Blood component dispenser or with all Dispensers within another region or a country.

(3) The Blood component *Producer* [**3.13**] prepares Blood components for transfusion from donor blood. In many countries the production process utilises a special Blood Transfusion Data System providing internal communications between the subdivisions (Blood Collection, Donation classification [**3.18**], preparation of Blood components [**3.47**], transformation of Blood components[**3.53**]).

(4) The *Laboratory Service provider* [**3.42**] provides a laboratory service (serological, biochemical, bacteriological and virological analyses). The laboratory can be an integral part of the healthcare organisation.

(5) The *Relay Store.* In some organisations, for example in France, this actor is physically very close to the user, but has a separate and distinct role to keep dispensed labile blood products [**3.41**] in special storage conditions.

Two groups of messages have been identified within Scope:

Group 1. Subject of care related messages (BTR – PAT)
Group 2. Production related messages (BTR – PROD)

The first group specify messages used in:

- TESTING ACTIVITIES
- TRANSFUSION ACTIVITIES

They consist of communications between the User, the Dispenser and the Laboratory. Acknowledgement messages are also required at different stages between the two parties.

The second group specify messages used in:

- production,
- dispensing,
- logistic activities,

They communicate messages between separately organised units within the Blood transfusion, production and dispensing process.

Communication between the following parties should be exchanged according to ENV 1613

- the User and the Laboratory
- the User and the blood transfusion service (testing unit)
- the blood transfusion service and the Laboratory

Group 1 Subject of care related messages :
This European Prestandard specifies 7 messages divided into two sub-groups concerned with:

1.Transfusion activities (activities directly related to the fact of transfusing blood components to patients):

Request for blood components (Blood components prescription)
Blood component recipient delivery note
Transfusion report

2. Testing activities (activities related to the fact of testing patients and blood products) :

Blood grouping request
Blood group report
Compatibility testing request
Compatibility test report

Group 2 Production related messages :
These messages are dependent on the organisation of the transfusion service provider and concerned with:

Donor clinical information
Blood component classification request
Blood component classification report
Blood component manufacturing request
Blood component issue delivery note
Blood component processing request
Blood component process delivery note

For example, in France, the Blood component dispenser uses a different procedure for Blood component recipient delivery from that for other forms of Blood component delivery.
In Scandinavia, the Laboratory Investigation service may be part of the transfusion service provider, the Request for blood components and Blood component recipient delivery notes being exchanged between hospitals.

Messages for the transmission of Requests for blood components, covered by the scope of this European Prestandard, shall enable electronic interchange of the semantic content defined in the General Message Descriptions for Request for blood components in clause 6.

Messages for transmission of Blood component recipient delivery notes, covered by the scope of this European Prestandard, shall enable electronic interchange of the semantic content defined in the General Message Descriptions for Blood component recipient delivery notes in clause 6

Messages for transmission of Blood component delivery notes, covered by the scope of this European Prestandard, shall enable electronic interchange of the semantic content defined in the General Message Descriptions for Blood component recipient delivery notes in clause 6.

When implementing information exchange based upon this prENV, all generated messages must be acknowledged by the receiver.

Messages for transmission of applicative acknowledgement of the above messages covered by the scope of this European Prestandard are defined at an application level (ISO 7). They do not interfere with similar messages at lower levels. These messages are reports that the target applicant has received the message, and whether or not the message can be processed normally (if appropriate it may include additional information).

Implementable message specifications (IMS) [**3.40**] shall conform to the General Message Descriptions defined in this prENV. They shall support both mandatory and optional objects, attribute [3.3] groups and attributes as defined in the General Message Descriptions of this prENV. They shall also support the relationships between objects as defined by the General Message Descriptions.

Implementable message specifications should be expressed in terms of a syntax that is an International Standard [**3.50**] except where the healthcare user requirements cannot be met by using such a Standard syntax.

When implementing information exchange based upon this prENV, data protection and confidentiality principles have to be guaranteed according to the laws actually in force in the different CEN member countries. The mechanisms needed to secure data integrity [**3.25**], data protection and confidentiality, authentication [**3.5**] of communicating parties and subjects of care are outside the scope of this prENV.

While the messages specified in this prENV may convey clinical and administrative information concerning subjects of care, the way in which this information is treated in this prENV does not constrain the development of future standards for the electronic healthcare record [**3.28**] or for other clinical and administrative messages.

The provisions of this prENV have been validated for the purposes described above. However, since the messages described in this ENV are designed for general application in the Blood transfusion domain, the users are required to decide for themselves whether or not these messages meet their particular requirements. A requirement for using other messages, e.g generic messages for cancellation or acknowledgement, in addition to or instead of messages specified in this prENV, does not invalidate the use of this prENV.

2 Normative References

The following normative documents contain provisions that, through reference in the text, constitute provisions of this draft European Prestandard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this draft European Prestandard are encouraged to investigate the possibility of applying the most recent editions of the normative documents below. For undated references, the latest edition of the normative document referred to apply. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 2382-4:1987	Information processing - Vocabulary Part 4: Organisation of data
ISO 5281 : 1997	Information interchange - Representation of human sexes
ISO/IEC 7826-1 : 1994	Information technology - General structure for the interchange of code values - Part 1 : Identification of coding schemes
ISO/IEC 7826-2 : 1994	Information technology - General structure for the interchange of code values - Part 1 : Registration of coding schemes
ENV 12539	Diagnostic services department request and report messages
ENV 1613 : 1995	Medical informatics - messages for exchange of laboratory informations

3 Normative definitions and abbreviations

For the purposes of this Draft European Prestandard (prENV), the following definitions (listed in alphabetical order) apply:

3.1
accountability
the property that ensures the actions of an entity can be traced uniquely to the entity

[ISO 7498 – 2]

3.2
assurance
development, documentation, testing, procedural and operational activities carried out to ensure a system's security [**3.49**] services do in fact provide the claimed level of protection

[OMG 97]

3.3
attribute
a characteristic of an object or entity

3.4
audit trail
record of the resources which were accessed and/or used by whom.
Note: This may involve a formal monitoring technique for comparison between the actual use of a medical information system and pre-established criteria

[ISO 7498 – 2]

3.5
authentication
the process of reliably identifying security subjects by securely associating an identifier and its authenticator

[ISO 7498 –2]

3.6
authorise
granting of rights, which includes granting of access based on access rights

[ISO 7498-2]

3.7
autologous transfusion
transfusion of any blood component that was donated by a donor who is also the subsequent recipient

3.8
availability
the property of being accessible and useable upon demand by an authorised [**3.6**]entity

[ISO 7498-2]

3.9
batch
amount of material which is uniform in character and quantity as shown by compliance with production and quality assurance requirements and produced during a defined validated process of manufacture. A labile blood product batch is identified by unique blood donation number.

[EN 375:1992 E][EN 376:1992 E]

3.10
blood
blood is a complex fluid, consisting of cellular components (approximately 45% of the total volume) suspended in a fluid environment, the plasma. It circulates in the arteries and veins of subjects of care and acts both as a transport system and as a defence mechanism, fighting infection

3.11
blood component (BC)
blood or a substance derived from blood that is or may be provided for administration to a subject of care or for production of medicinal products. There are two kinds of Blood components:
labile blood products – red blood cells; fresh frozen plasma; platelets; cryoprecipitate; white cells; progenitor cells collected from peripheral blood (stem cells) and plasma derivatives – these are partially purified human plasma proteins made under pharmaceutical manufacturing conditions, including coagulation factors, immunoglobulins and albumin.

3.12
blood component dispenser

a person or other entity who obtains blood components from one or more providers. The Blood component dispenser stores Blood components in order to assemble, prepare or dispense a Blood component in accordance with a specification furnished by a Blood component requester [**3.14**] .
(In UK and in Scandinavia, a blood component dispenser is a Hospital Transfusion Laboratory)

3.13
blood component producer
a person or other entity authorised to prepare blood components for transfusion from donor blood. The entity authorised to prepare blood components may be a manufacturer or a processor.

3.14
blood component requester
a person (usually a healthcare professional) who establishes the need for a transfusion of blood for a specific subject of care and makes a request to the blood component dispenser to obtain blood components for administration as a transfusion

3.15
blood component user
a healthcare professional who performs blood transfusions to subjects of care

3.16
blood group
one of several classifications into which the blood may be grouped. It is determined by the presence of specific antigens on the surface of the erythrocytes

3.17
blood transfusion
the administration of blood components obtained and processed from blood donors into the bloodstream of a recipient

3.18
classification of blood donation
the set of operations related to biological tests performed in laboratory investigation services, aimed to establish the immuno-haematologic characteristics of the blood donated and to evaluate the safety of the blood donated to prevent the transfusion of transmitted diseases, based on formal legal requirements

3.19
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

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

[CEN ENV 1613:1995]

3.20
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 [**3.22**] for three-letter abbreviations of airport names.

[ENV 7826][ISO/IEC 7826]

3.21
code value
result of applying a coding scheme to a code meaning [**3.20**]

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

[ENV 7826] [ISO/IEC 7826][ISO 2382:1987, modified]

3.22
coding scheme
Collection of rules that map the elements of one set on to the elements of a second set

[ISO/IEC 7826][ISO 2382-1987, modified]

3.23
confidentiality
the property that information is not made available or disclosed to unauthorised individuals, entities or processes

[ISO 7498-2]

3.24
consent
voluntary agreement with what is being done or proposed (express or implied)

[CIHI]

3.25
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 system assets must 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]

3.26
domain information model
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]

3.27
edifact
Electronic Data Interchange for Administration, Commerce and transport. They comprise a set of internationally agreed standards, directories and guidelines for the electronic interchange of structured data (Also referred to as UN/EDIFACT)

3.28
electronic healthcare record
healthcare record concerning the subject of care in computer readable form

[CEN ENV 13606-1]

3.29
general message description
subset of a domain information model [**3.26**] prescribing the information content and semantic structure of a healthcare 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 a statement of the information interchange requirements in a form that can be implemented using different syntaxes.

[CR 12587][ENV 1613]

3.30
healthcare
provision of health related services

NOTE 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.

[CEN TC/251 PT30]