

Medical Informatics — Methodology for the development of healthcare messages

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National foreword

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Méthodologie pour le développement des
messages dans le domaine de la santé

Methodik für den Entwurf von Nachrichten
(Inhalte, Strukturen) im Gesundheitswesen

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Foreword

Method for the development of healthcare messages

This CEN Report has been prepared under the direction of the European Committee for Standardisation (CEN) and is being submitted for approval by CEN/TC251 "Medical Informatics".

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The members of this project team were:

Sigurd From, Norway

Raphaël Hacquin, Belgium

Andrew Hinchley, United Kingdom

Brian Love, United Kingdom

Yves Mounier, France

Dirk Segers, Belgium (project team leader)

Jorgen Bruun Svendsen, Denmark.

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Introduction

The main goal of WG3 is to develop standardised healthcare EDI messages. To ensure the overall consistency and coherence between the various standard messages (to be) developed, it is important that the message development activities conducted in a variety of domains are based upon the same approach and that the resulting deliverables are structured and presented consistently. The goal of this CEN Report is to describe the method to be used for the definition of character-based EDI messages to be used in healthcare, as currently no adequate method exists for this purpose¹⁾.

The method builds upon and extends the approach as defined and used so far by WG3 (see CR 1350:1993 and the European Prestandard for the messages for exchange of laboratory information), and contains the following main components:

- establishment of the user requirements in the selected healthcare messaging domain.
- both an informal and formal specification of the messaging scenarios. This includes the definition of the communication roles, the messaging services (functions) to be supported by these roles and the major interrelationships between the EDI message types required to cover the needs for a particular domain.
- the formal definition of the information that is shared between the communication roles, through the Domain Information Model.
- the formal definition of the messages required to support the information exchange needs (General Message Descriptions), independently of the EDI-syntax used for the implementation.
- how to translate the General Message Descriptions into hierarchical structure specifications for implementation using a standard EDI-syntax,
- how to develop Implementable Message Specifications using a standard EDI-syntax (e.g. ASN.1 and EDIFACT).

The report specifies the method to be used by CEN/TC 251/WG3 in particular, but the underlying principles may be used by other CEN/TC 251 working groups and even outside the healthcare messaging domain.

The main clauses are clause 4 and 5. Clause 4 is a summary of the overall activities in the context of the development of standard messages, clause 5 defines each activity covered by the scope of this report in detail.

The annexes deal with issues arising related to the approach:

- Annex A positions the message development approach in the context of the overall healthcare communications framework and in the overall context of standards,
- Annex B describes a number of management issues related to the message development process (iteration, process management, quality assurance activities, project team organisation),
- Annex C defines the attribute data types, used for the specification of the messages, in detail.
- Annex D gives 2 additional approaches for the transformation of an object-oriented general message description into a hierarchical general message description.
- Annex E deals with the aspects when moving to implementation (mainly profiling, i.e. customisation of the message specifications towards local implementation needs).
- Annex F clarifies the scope of this method when considered in the context of more tightly coupled systems.
- Annex G is a paradigm annex on how to read the models included in messaging standards based upon this approach
- Annex H is an executive summary of the approach.

¹⁾ Most methods are oriented towards the development of systems. This approach aims specifically at the definition of standardised EDI messages, in such a way that these specifications are complete, independent on the underlying implementations (implying a longer life-cycle for the specifications), easy to understand by the end-users and usable towards system developers.

How to read and use this document:

If you are new to the work of CEN/TC 251/WG3, and if you want to get the essential information about the way the Working Group develops standardised messages: after this introduction:

- 1) Annex A,
- 2) Annex H (executive summary)
- 3) clause 1 (scope),
- 4) clause 4 (message development overview).

If you know a little about the approach as used by the Working Group, and if you want to get more familiar with it:

- 1) Annex A,
- 2) clause 1 (scope),
- 3) clause 4 (message development overview) or Annex F (executive summary)
- 4) clause 5 (detailed message development activity description) or Annex G (summary of symbols).

If you are knowledgeable about the approach and the activities of CEN/TC 251/WG3, and if you want to apply it for a specific message development task:

- 1) clause 1 (scope),
- 2) clause 4 (message development overview),
- 3) clause 5 (detailed message development activity description),
- 4) Annex B (message development process management issues),
- 5) use Annex C for issues arising related to attribute data types,
- 6) use Annex D for the troubleshooting related to the construction of hierarchical GMDs,
- 7) use Annex E for the modification of the resulting message specifications to more local information exchange needs,

If you want to use the deliverables resulting from a message development group which followed the approach:

- 1) Annex H (executive summary),
- 2) clause 4 (message development overview),
- 3) clause 5 (detailed message development activity description) or Annex G (summary of symbols).

1 Scope

The scope of this CEN report is to specify a method for the development of European Standard message specifications for the electronic exchange of structured character-based information, between autonomous computer systems within and between organisations, for purposes related to healthcare. Such message standards are essential if healthcare services are to obtain the benefits of open systems and avoid the constraints of proprietary interfaces. The method specifies the activities of the message development process and the structure and the components of the resulting deliverables.

The scope of this report does not include method specifications for the development of other subject areas covered by working groups of CEN/TC 251, EWOS EG-MED and WEEB/MD9.

The scope covers the development process of standardised messages, starting from the user requirements up to the delivery of message specifications using EDIFACT and ASN.1, the two international syntax standards selected in view of CR 1350:1993, but the report does not exclude other syntaxes (e.g. SGML) from being used for the syntax specific message specifications.

The scope of the Report is limited to the specification of standardised messages, therefore it does not include in its scope areas such as conformance testing of messaging applications, the implementation method for messaging standards, the maintenance of the messaging standards. It does not include in its scope issues relating to data secrecy and data protection. It does not specify methods for establishing directories of coding schemes, for data sets or for messages. It does not include specifications related to the messaging standards approval process.

The method defined by this CEN Report supports and is validated for the development of message specifications for the electronic exchange of structured character-based information in healthcare, but it does not by its nature exclude the method to be used in a wider domain (i.e. other types of information or other domains).

2 References

This report incorporates by dated or undated reference, provisions from other publications. These references are cited in the appropriate places in the text and the publications are listed hereafter.

CR 1350:1993, *Investigation of syntaxes for existing interchange formats to be used in Healthcare*.

ENV 1068:1993, *Medical Informatics — Healthcare information interchange — Registration of coding schemes*.

ENV 1613:1994, *Medical Informatics — Messages for the exchange of laboratory information*.

ISO 646:1991, *Information technology — ISO 7-bit coded character set for information interchange*.

ISO 2382:1987, *Information processing — Vocabulary — Part 4: Organisation of data*.

ISO 6523:1984, *Data interchange — Structure for the identification of organisations*.

ISO 8824-1:1993, *Information technology — Open Systems Interconnection — Abstract Syntax Notation One (ASN.1) — Part 1: Specification of basic notation*.

ISO 8825-1:1993, *Information technology — Open Systems Interconnection — Specification of ASN.1 encoding rules — Part 1: Basic Encoding Rules (BER)*.

ISO 8601:1988, *Data elements and interchange formats — Information interchange — Representation of dates and times*.

ISO 8859:1987, *Information Processing — Registration of graphics character subrepertoires — Eight-bit single byte coded graphic character sets*.

ISO 9735:1992, *Electronic data interchange for administration, commerce and transport (EDIFACT) — Application level syntax rules*.

1991, *CEN/CENELEC Internal Regulations: Part 3: Rules for the drafting and presentation of European Standards (PNE-Rules)*.

ISO/IEC JTC1/WG3 N255:1994-01-31, *Open-edl Reference Model Standard — Working Draft*.

ISO/IEC JTC1/WG3 N268:1994-03-28, *Concepts and notations for Open-edl Scenarios*.

3 Definitions & Acronyms

3.1 Definitions

For the purposes of this report, the following definitions (listed in alphabetical order) apply:

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

[ENV 1068]

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.

[ENV 1068]

[ISO 2382-1987], modified

coding scheme

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

[ENV 1068]

[ISO 2382-1987], modified

communication party

the party involved in the communication

communication role

the role of a party related to communication

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

NOTE 1 In this report the abbreviation DIM is used.

NOTE 2 The DIM may be regarded as, but is not necessarily limited to, a super-set of the General Message Descriptions defined for a given healthcare EDI domain.

general message description

subset of a domain information model prescribing the information content and semantic structure of a healthcare message used to meet one or more identified information interchange requirements

NOTE 1 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.

NOTE 2 In this report the abbreviation GMD is used.

GMD profile

specification derived from an general message description, supporting all the GMD mandatory components, but supporting a subset only of the GMD optional elements, appropriate to the specific business requirements of the communicating parties

healthcare coding scheme designator

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

healthcare EDI application

the functional and technological solution which supports a healthcare EDI service

healthcare EDI domain

a practical grouping of the healthcare EDI services for the purpose of standardisation which sets the scope for a H-EDI standard

EXAMPLE: Information interchange in clinical chemistry

healthcare EDI service

the medical or administrative service provided by one healthcare party to other healthcare parties by use of EDI

healthcare message

an identified, named and structured set of functionally related information which fulfils a specific healthcare business purpose in the context of information interchange

hierarchical general message description

a general message description specified using a strictly hierarchical structure with the same functionality as the corresponding non-hierarchical general message description

NOTE 1 A hierarchical general message description must have a single root.

NOTE 2 A lower level component of a hierarchical general message description must always have exactly one parent component.

NOTE 3 In this report the abbreviation H-GMD is used.

implementable message specification

specification of a general message description in a particular message syntax

NOTE In this report the abbreviation IMS is used.

IMS profile

specification derived from an implementable message specification, supporting all the IMS mandatory components, but supporting a subset only of the IMS optional elements, appropriate to the specific business requirements of the communicating parties

message syntax

system of rules and definitions specifying the basic components, their interrelationships and their arrangement within messages

3.2 Acronyms

ASN.1:	Abstract Syntax Notation One
DIM:	Domain Information Model
EDI:	Electronic Data Interchange
GMD:	General Message Description
HCD:	Healthcare Coding Scheme Designator
H-EDI:	Electronic Data Interchange in Healthcare
H-GMD:	Hierarchical General Message Description
ICD:	International Coding scheme Designator
IMS:	Implementable Message Specification
MIG:	Message Implementation Guidelines
PNE-rules:	the rules for the drafting of European Standards
UN/EDIFACT:	United Nations Electronic Data Interchange for Administration, Commerce and Transport
UNSM:	United Nations Standard Message

4 Summary of the overall activities in the context of standard healthcare EDI message development

The method described here builds on the recommendations contained in the CEN Report produced by CEN/TC 251 (Medical Informatics) on "Investigation of syntaxes for existing interchange formats to be used in Healthcare" (CR 1350:1993). The application of the method for message development purposes by CEN/TC 251/PT3-008 in the domain of messages for the exchange of laboratory information and the experience of users in identifying and agreeing implementable subsets at national or more local level have made a particular contribution to this approach.

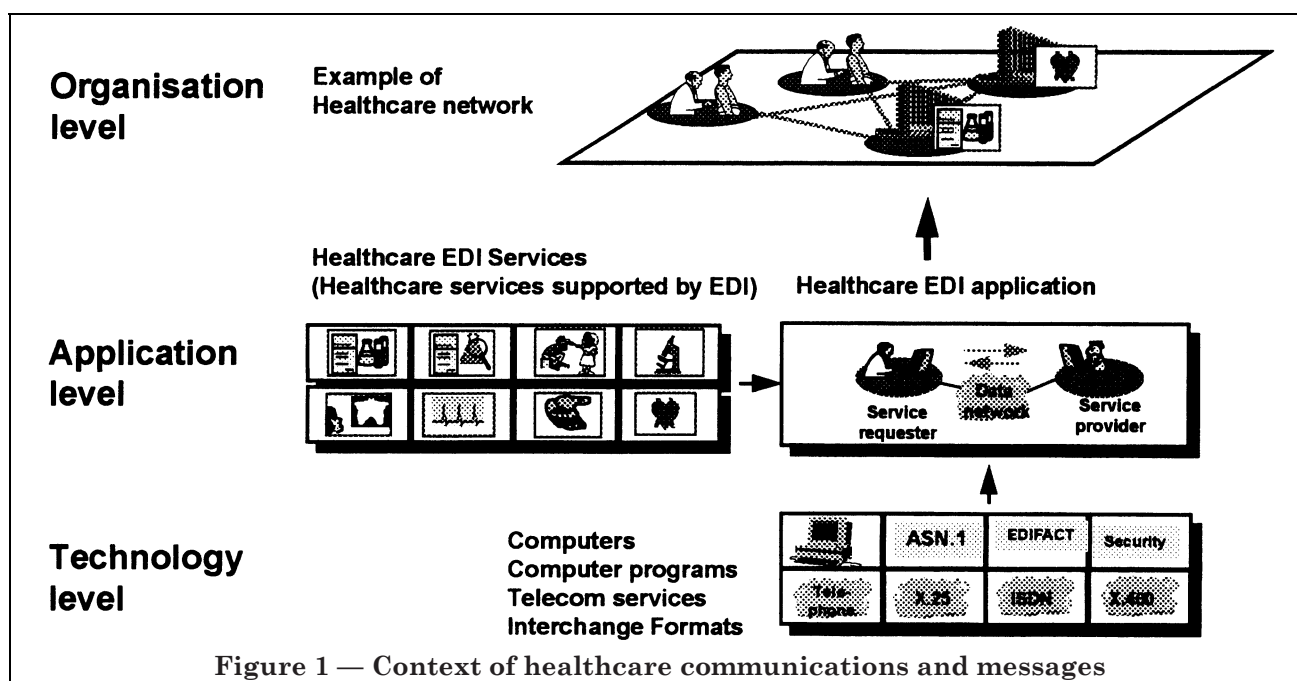
4.1 The context and purpose of the message development activity

NOTE 1 see Annex A for a detailed description of the healthcare communications framework.

The increased used of computer systems and computer networks has created a new generation of healthcare EDI-applications (H-EDI applications). An example of a H-EDI application is the exchange of laboratory requests and reports between GP medical record systems and laboratory systems via EDI.

When developing these applications, the healthcare aspects (end-user requirements, privacy needs,...) and the technological aspects (EDI-syntaxes, computer platforms...) must be considered together with the organisational context where the H-EDI application is to be used.

The objective of a H-EDI application is to support healthcare EDI services (H-EDI services). Examples of H-EDI services are the electronic transfer of information related to the ordering and reporting of laboratory investigations, radiological investigations, admission and discharge to and from hospital, statistical information related to healthcare activities, transfer of medical records, reimbursement, etc...



H-EDI-services define the purpose of the communication between the communicating parties and thus the purpose for the messages exchanged between these parties. Based on the H-EDI-service needs, the information required for the interchange can be determined.

In order to obtain the objective of EDI which is to ensure unambiguous interpretation and a shared understanding of the data in a message, it is essential that only commonly defined information is exchanged with EDI. There is, therefore, a need to determine the information which is to be exchanged between the parties involved in the communication.

An EDI standard message enables the transfer of structured computer processable information conforming to agreed standards, from one independently managed computer system to another.

The purpose of the message development activity is to use the healthcare requirements, the technological solutions, the organisational needs (including existing standards in these areas) for the development of a standard EDI message specification, implementable by system developers and satisfying the user needs. This report addresses the method within the overall context of the message development activity.

4.2 The overall standard message development process

The message development activity is basically a three-fold process:

- it starts with the identification of the healthcare EDI messaging needs,
- the activities part of the message development approach described in this report are the central component,
- it ends with the preparation for implementation of the standardised messages.

After implementation change management mechanisms are required for all message development results.

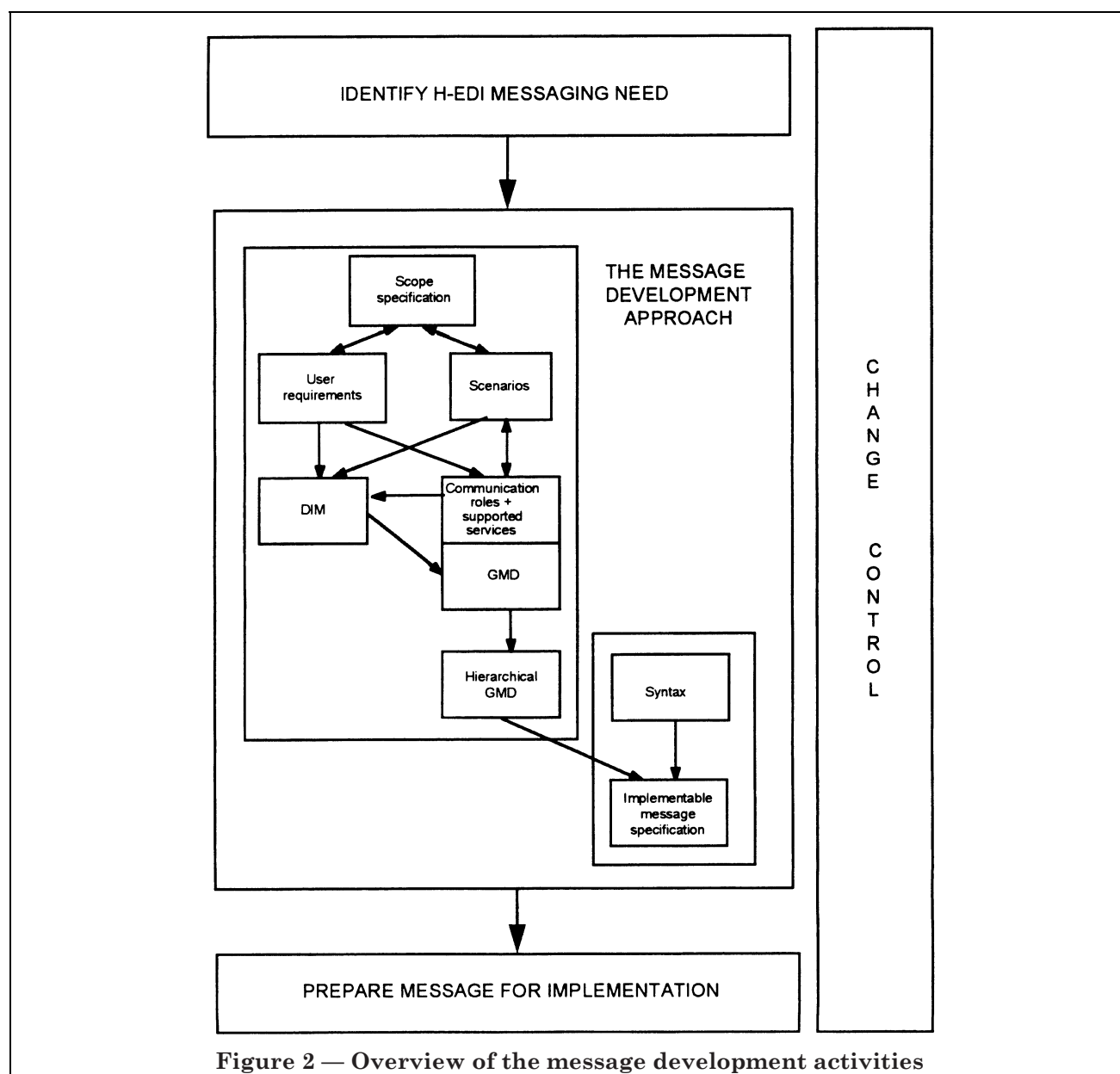


Figure 2 shows the overall steps in the process. Each component is briefly described hereafter. Chapter 5 specifies the message development approach activities in detail.

4.2.1 Identify healthcare messaging need

The identification of the need for standardised messages to support certain H-EDI services is usually originated by interested user groups. A judgement on the feasibility of defining standardised EDI messages for the requested area will be made and an initial scope of the message development work will be drafted.

4.2.2 The message development approach

Once an initial scope is available, the message development activities, which correspond with the scope of this report, can start.

Each of these steps is summarised hereafter and described in detail in chapter 5.

Remarks:

- although the process is presented sequentially, the real world process is iterative.
- during each activity, the available standards and directories corresponding to the domain covered should be considered.
- project management and quality assurance activities are detailed in annex B.3.

The activities to be performed are:

- specify the scope of the message development work,
- describe scenarios,
- specify user requirements,
- define the communication roles and the supported services,
- elaborate the domain information model (DIM),
- specify the required general message descriptions (GMD),
- derive the hierarchical general message descriptions (H-GMD),
- build implementable message specifications (IMS).

4.2.2.1 *Define scope of the message development activity*

The first step of the message development activity is the specification of its scope starting from the identified need for standardised EDI messages in a given healthcare domain.

The scope of a healthcare messaging standard covers the specification of:

- the H-EDI domain which is involved,
- the information flows for which standardised messages are to be developed,
- the main communication parties and roles (including high level scenario descriptions).

The scope must make clear:

- the practical impact of the standard to its users,
- the parties to which the standard applies so that these can be informed about its existence,
- the general real world cases where the standard shall be used.

The scope of the **information content** of a messaging standard will be greater than the information requirements for which all potential users have a common requirement and will include optional data which will be of interest only to a subset of the user community.

The only **behavioural dimension** of the communicating parties that should be included in the scope is the external behaviour of the communication role. Any expected behaviour at the application services supported level should not be included in the EDI message standard specification.

4.2.2.2 *Describe scenarios and specify user requirements*

After the initial specification of the scope, a set of scenarios (i.e. textual descriptions of real world cases where the messages defined by the standard should be used) are drafted.

The scenario specification:

- extends the high level scenarios of the scope statement,
- gives examples of healthcare parties acting in the scenarios,
- considers variances of the message exchange patterns,
- describes real world situations where the messages defined by a standard may be used, but may equally specify explicitly real world situations where the messages were not intended to be used.
- is of an illustrative nature, but the results are used for the formal specification of the normative components.

The key source of information for this activity are domain specialists (users). Other sources are the scope statement, existing standard messages, existing definitions and concepts, existing H-EDI applications in the domain, etc...

The process of gathering the user requirements provides the input for the subsequent modelling steps, and has the following steps (usually performed in parallel):

- requirements gathering (see sources above)

- selection of the concepts subject to information exchange and of information exchange patterns to be considered for further elaboration,
- extension and refinement of the selected concepts.

Agreement on the list of concepts resulting from this activity is an important step in achieving consensus on the user requirements. This list of concepts is subject to further refinement in the subsequent steps of the process.

4.2.2.3 Define the communication roles and the supported services

The communication roles and supported services specification:

- identifies the communication roles implied by the standard (completed with examples as required),
- identifies the GMDs defined by the standard,
- establishes the relationship between each communication role and the GMDs defined by the standard,
- defines the external behaviour required for each communication role (i.e. the services to be supported by each communication role in relationship with its associated GMDs).

The communication roles and supported services specification is used to:

- identify the healthcare parties implied by the messaging standard,
- define, in a generic way, the business scenarios supported,
- identify the messages for which the standard gives contents specifications and the association between the communication roles and these messages (through models depicting the domain information flow),
- validate applications for compliance against a given communication role.

The main input to the process is the textual scenario specification. The components of the scenario descriptions are formalised through a **generalisation and abstraction** process:

- of the healthcare parties towards communication roles.
- of the patterns of the information exchanged towards the GMDs to be defined.
- of the scenario descriptions to the association between the communication roles and the GMDs and to the services required to be supported by each communication role.

4.2.2.4 Create Domain Information Model (DIM)

The DIM is a static model of those concepts from the relevant H-EDI domain which need to be exchanged between communicating parties.

The DIM identifies for the purpose of managing information exchange, the individual items or objects (people, things, concepts) that are relevant and the structured relationship between them — e.g. what items are parts of another item or concept. Only those concepts in the H-EDI domain which need to be exchanged by the communication parties should be included in the model.

The DIM should not attempt to model the information processing requirements of applications and information related to the internal processes in an application programme should be omitted. Common concepts in healthcare may be reused in several H-EDI domains, but the exact instantiation in terms of objects and related attributes in any DIM will reflect the requirements of the specific information exchange domain being modelled.

The DIM provides detailed information of each object and its attributes. The objects and attributes in the DIM are built up from the information requirements identified by users. The attribute layer specifies the lowest level of the data (the basic building blocks) used to express the information to be exchanged.

The DIM will relate to a family of messages from the specified H-EDI domain. There should be a consistent allocation of attributes to objects within the specific H-EDI domain covered by an individual DIM. The definition of objects and attributes should be based on their usefulness in assisting in the definition of the information requirement of a GMD.

4.2.2.5 Create General Message Descriptions (GMDs)

A message incorporates a selected amount of information which is exchanged between two systems for a given purpose. The GMD is a special view of the overall Domain Information Model (DIM) reflecting one message type. The GMD prescribes the information content and semantic structure of a message used to meet an identified information exchange requirement by detailing the objects and attributes to be conveyed in the message. GMDs will contain some or all of the objects in the DIM. Each object in the GMD will refer only to the attributes required for the pattern of information exchange for which the GMD is specified.

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

The GMDs are the most important syntax independent result of the message development activities.

4.2.2.6 Derive hierarchical general message description (H-GMDs)

Current EDI-syntaxes are designed to provide serial expressions of information. The GMD- specifications are network structures and therefore their transformation to a hierarchical structure is required.

The purpose of defining hierarchical GMDs (i.e. a single hierarchical derivation for each GMD) is to:

- leave no room for creating ambiguity, while staying independent from EDI syntaxes,
- allow easy conformance checking of the syntax specific messages,
- ease conversion between syntax specific messages,
- ease the specification of the GMDs in syntaxes currently used for EDI (e.g. EDIFACT).

The hierarchical GMD is a syntax independent specification and must not be biased towards a particular syntax.

4.2.2.7 Develop Implementable Message Specifications (IMS)²⁾

An Implementable message specification (IMS) is the specification of a GMD or a hierarchical GMD in a particular EDI-syntax, such as EDIFACT or ASN.1. The IMS defines the structure, rules and constraints that will be determining the content and form of actual messages exchanged.

An Implementable Message Specification must comply with the following rules:

- be derived from a specific H-GMD³⁾;
- support mandatory and optional objects, attributes, attribute groups as defined in the related GMD;
- the IMS shall support the cardinality constraints as defined by the GMD. Limitations, based upon real-world cases may be introduced when required by the supporting syntax;
- be defined in terms of a syntax which is an international standard, except where the healthcare user requirements cannot be met.

The development process of the IMS depends on the syntax selected.

(1) EDIFACT

The development of the EDIFACT specification starts from a hierarchical GMD.

It may be appropriate for one EDIFACT IMS to support more than one GMD.

The EDIFACT IMS consists of a UNSM standard message, together with any additional specifications needed to support the IMS.

The required action is to fit the hierarchical GMD to an appropriate existing or new structure. Any security/confidentiality requirements to be incorporated at the message level should be included.

Data element directories and coding schemes are searched and appropriate items with relevant information on concrete presentation (number of characters, alphabetic/numeric, value ranges etc.) are extracted to match the requirements of the GMD. Where appropriate new items or amendments should be proposed to these directories and coding schemes to enable standard messages to be developed.

²⁾ The preceeding results (i.e. scope, communication roles and supported services, DIM, GMDs and H- GMDs are in the context of standardised character-based healthcare messages progressed under the auspices of CEN/TC 251 (as normative CEN standards). The implementable message specifications are progressed under the auspices of the body in charge of the syntax standard used for the IMS. In case of EDIFACT this is the Western European EDIFACT Board.

³⁾ The IMS may equally be developed from the GMD, in those cases where the syntax supports the GMD-structures appropriately. This possibility is not shown in Figure 2, which only shows the more general case with the syntaxes currently used.

Objects, attributes and structures are transformed in the corresponding EDIFACT syntax components (data elements, segments, segment groups, hierarchies of segment groups).

(2) ASN.1

To ensure consistency in the ASN.1 message specifications the following guidelines must be considered:

- naming conventions (typographical conventions to be used),
- how to specify the attribute data types in ASN.1,
- guidelines related to the tagging (identification) of message components,
- transformation from a hierarchical GMD structure towards ASN.1 specifications.

As in ASN.1 no mapping with existing directories is required, the transformation of the hierarchical GMDs towards the syntax specific structure is a straightforward process.

4.2.3 Prepare message for implementation

The results of the message development process are generic implementable message specifications in a given syntax. The resulting specifications need to be completed before they can actually be implemented by a group of system providers. Some steps of this process are:

- the determination of the scope of the actual implementation (usually, but not necessarily, national),
- the selection of coding schemes to be used for the representation of coded values,
- the determination of the profile(s) that will be used,
- the development of message implementation guidelines in the requested syntax,
- the selection of the character set(s) that will be used.

The message documentation in the international EDI syntax selected for implementation should describe how the structure and content of the GMD is mapped to the implementable message specification.

At the level of the “community” which will use the message for achieving their business purposes there is a requirement for a detailed document which describes the information, including the selection from the options for coding schemes etc., which they have agreed to exchange. In the EDIFACT community this is known as a Message Implementation Guideline document (MIG).

It will also indicate which coding schemes are considered mandatory or are preferred. The MIG at the user community level will also specify the required IMS profile, i.e. which of the optional (or conditional) elements in the IMS are considered mandatory by users and the rules that should be followed relating to the dependencies between optional information. Decisions on the presentation format of the message implementation guidelines (other than any rules that may be associated with the selected syntax), including decisions on whether to include the GMD and mappings to the GMD are for local decision. All local or community level versions of the messages shall remain consistent (as a true subset) with the standard IMS and the GMD specification to which it relates.

Apart from some general principles related to profiling (see Annex E), this report does not address this user community level process.

4.2.4 Change control

Any message developed will have a lifecycle determined by the business needs of healthcare. The same applies to the DIM, GMDs, IMSs. The concept of a “version” of a DIM, GMD, IMS etc. is important. The requirements and agreed definitions of information that needs to be shared between, for example, GPs and hospital consultants, will be subject to change over time. New versions will require to be agreed upon from time to time to reflect this.

Messages development deliverables should be allocated version numbers to enable effective management of the change control process. The mechanisms for version assignment and version control of message development deliverables reside with the organisation in charge of the maintenance of these deliverables and shall be compliant with the procedures these organisations have for this purpose. New versions of these deliverables imply that all derived results need to be reviewed for compliance with the revised specifications (e.g. when a GMD changes, the H-GMDs and the IMSs will be likely to be affected).

The change control activities are not further detailed in this report.

4.2.5 *Electronic Data Interchange Agreements*

Implementation of EDI requires not only a common understanding of the detail contained in message documentation describing the information in the message but also an agreement which defines the necessary rules and relationships between parties which will govern their use of EDI. These agreements are generally referred to as Interchange Agreements. One such agreement, the “European Model EDI Agreement” — dated October 1994 has been recommended by the European Commission. It specifies the legal terms and conditions under which the parties conducting transactions by the use of EDI operate. The agreement sets out model legal provisions in a number of articles:

- 1) Object and Scope
- 2) Definitions
- 3) Validity and Formation of Contract
- 4) Admissibility in evidence of EDI messages
- 5) Processing and Acknowledgement of Receipt of EDI messages
- 6) Security of EDI messages
- 7) Confidentiality and protection of personal data
- 8) Recording and storage of EDI messages
- 9) Operational requirements for EDI
- 10) Technical specifications and requirements
- 11) Liability
- 12) Dispute resolutions
- 13) Applicable law
- 14) Effect, modification, term and severability

The Legal Provisions are intended to deal mainly with matters relating to substantive legal issues. The Technical Annex is the complement of the Legal Provisions in which the parties will have to determine all the technical requirements and specifications which are required in order to properly exchange EDI messages.

5 Message development activities: detailed description

Figure 3 depicts the overall activities related to the specification of standardised healthcare EDI messages. This chapter details each activity part of the message development approach rectangle on Figure 3.

NOTE some components of some drawings contain very small text to illustrate the textual nature of the results represented. This text is not intended to be readable.

5.1 Scope specification

5.1.1 Introduction

The clear, unambiguous specification of the scope of the message development activity is a **prerequisite** for any message development work. Basically any message development activity starts from a given, well-defined area of the healthcare activities for which standard messages are required. This **subdivision of the healthcare domain** in areas within which messaging standards are specified is however **outside the scope** of this report.

Although the scope of a messaging standard is defined by the functionality of the messages defined (and therefore easy to make once the messages are specified), the message development activity must start from a scope statement in order to delineate the areas of applicability and to enable the message developers to decide what is in- or outside their responsibility domain.

The PNE-rules give a number of guidelines on the wording of the scope clause in an international standard.

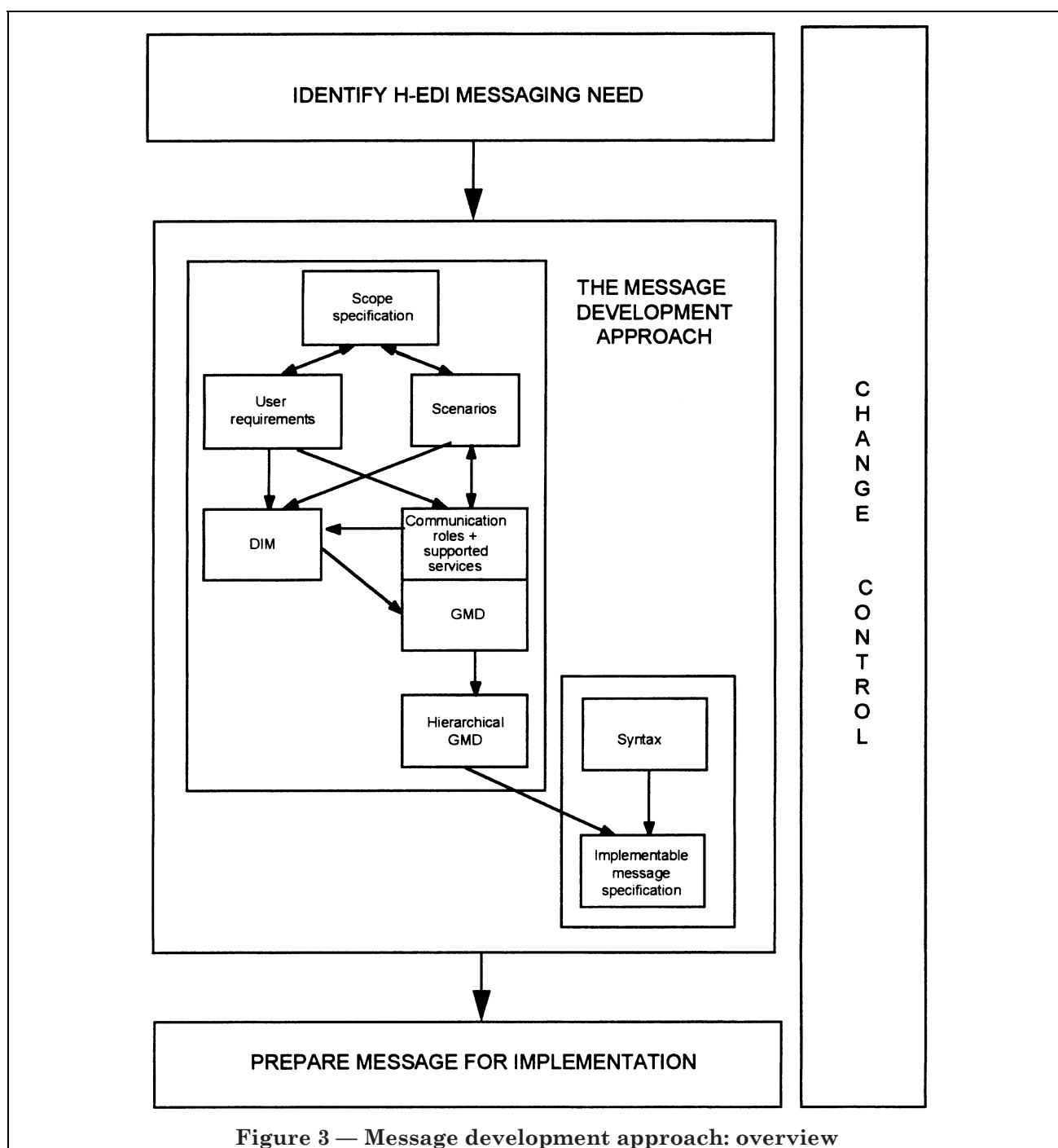


Figure 3 — Message development approach: overview

5.1.2 What, why

The scope of a healthcare messaging standard covers the specification of:

- the healthcare professions which are involved,
- the messages defined,
- the main communication parties and roles.

The scope may also indicate when appropriate:

- healthcare professions not specified by the standard but which are related to healthcare professions specified by the standard,

- identify areas for which the resulting message standards may be used but which were not validated against the functionality offered by the standard,
- functionalities related to the scope of the standard but which are not covered by it.

The components which are not covered within the scope may need specification due to country dependent healthcare organisational differences which might lead some readers to assume that certain areas are within the scope where actually they are not.

The scope must allow the definition of:

- the practical impact of the standard to its users,
- the parties affected by the standard so that these can be informed about its existence,
- the general real world cases where the standard shall be used.

5.1.3 *Process overview*

The specification of the scope (see Figure 4) should be done by domain specialists and:

- 1) may start from a “high level” statement of requirements which usually contains indications of the likely scope of the message development effort.
- 2) has to consider the existing standards, and identify messages already covering (part of) the user needs in the problem domain. Areas for which satisfactory standards exist may be ruled out of the scope or may be included through reference only.
- 3) is developed using the high level user needs, based on general scenarios which outline the messages and the functionality that will be required within the domain.
- 4) results in a scope statement, which identifies these areas for which the messages have been validated, but which may also identify areas for which the resulting messages may be used, but where the message has not been validated against the specific requirements.

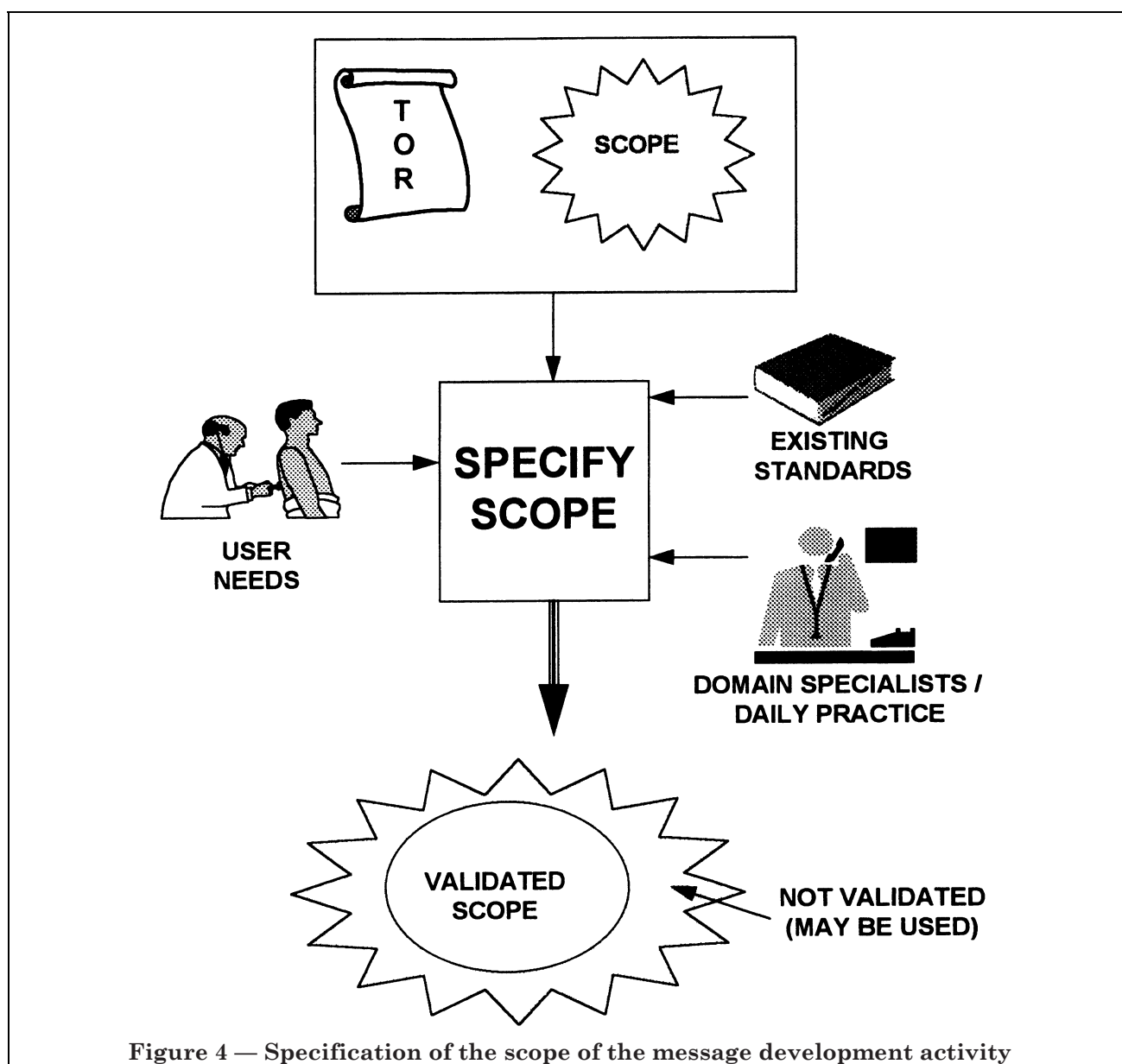
5.1.4 *When*

Required as from the **start** of the message development activities, the scope statement must be **continuously considered** in order to avoid deviation from it and in order to amend it to better fit the user requirements when needed. A first review can best be performed after the specification of the scenario descriptions to remove any remaining ambiguities. A final check is performed once all other parts are finalised (e.g. to verify the terminology and to re-validate whether the results correspond exactly with the scope).

5.1.5 *Specific guidelines*

5.1.5.1 *How to achieve quality*

Ideally the scope is defined in such a way that the information exchanges covered satisfy the more typical communication requirements **for the complete business cycle** in the selected healthcare domain. Before embarking on developing messages to meet less typical user requirements it may be relevant to evaluate the likely complexity and cost-effectiveness of implementing the messages.



5.1.5.2 Commonality of user requirements

The scope of the **information content** of a messaging standard should not be limited only to those requirements which are common to all the potential users of the standard message. Such a standard would lead to a minimal specification of the information exchange requirements which would be of little practical use to all or most users. In some instances there may be some **overlap** between messaging domains with the consequence that messages that are developed to meet the needs of one domain could in certain situations meet the needs of another domain and overlap with the scope of a message developed for that domain. In such cases the communicating parties should specify in an Interchange Agreement which message type to use for a particular business purpose. It is recommended that the scope statement of a messaging standard specifies clearly the areas where such decisions may be required.

5.1.6 Scope Specification: summary

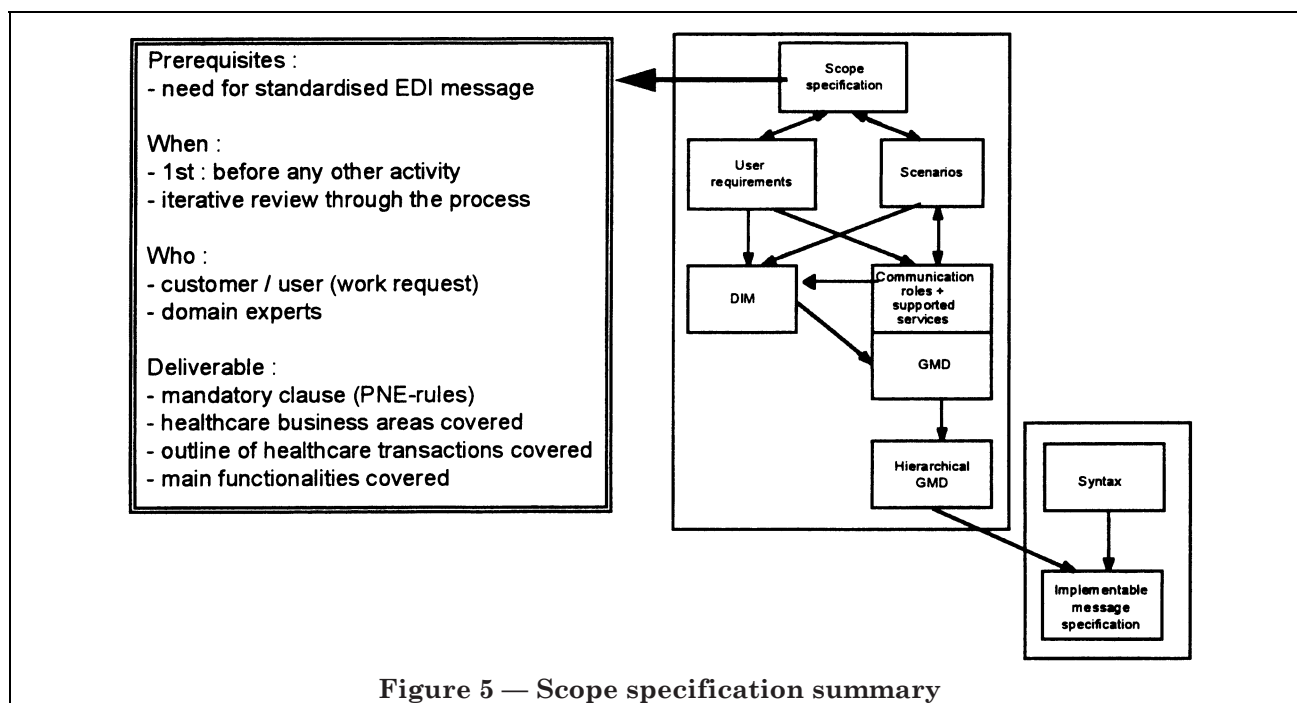


Figure 5 — Scope specification summary

5.1.7 Scope Specification: example

Extract from the scope statement of: Messages for exchange of laboratory information.

NOTE this statement (for a European Prestandard) is included here as an example that can be used as a paradigm for other messages standards. The italic representation is used to indicate that this text is strictly illustrative in this report.

This European Prestandard specifies general messages for electronic information exchange between clinical laboratories' computer systems and computer systems used by healthcare parties requesting the services of, or receiving results from, clinical laboratories (abbreviated as laboratories in this Prestandard).

This European Prestandard is applicable to messages requesting or reporting on the results of the services of the following specialties:

- Clinical Chemistry;
- Clinical Biochemistry;
- Toxicology;
- Clinical Immunology;
- Immunohaematology;
- Haematology;
- Clinical Microbiology (including Bacteriology, Mycology, Parasitology and Virology).

This European Prestandard is not applicable to messages requesting or reporting on the results of the services of the following specialties.

- Anatomic Pathology;
- Histopathology;
- Cytology; and
- Autopsies.

This European Prestandard does not specify the manner in which clinical laboratory services are divided between specialties as this varies in accordance with different national and local practices.

The scope of the messages specified by this European Prestandard comprises requests and results related to investigations carried out by clinical laboratories on subjects of investigation. This European Prestandard is applicable whether the healthcare party communicating with the clinical laboratory is a person (such as a doctor or other healthcare professional) or an organisation (such as a hospital, clinic or department). A clinical laboratory may itself act as the healthcare party submitting requests to, or receiving results from other clinical laboratories. However, this European Prestandard has not been developed to meet the needs of messages that are specific to communications between one clinical laboratory and another.

This European Prestandard is applicable to requests for investigation and modifications and cancellations of previously issued requests. It is applicable both to samples that are obtained from subjects of investigation at the point of care or at any other location and submitted to the clinical laboratory, and to requests for investigation for which the laboratory is requested to obtain samples. The messages it specifies support standing orders for laboratory services.

This European Prestandard is applicable to reports of the results of investigation and modifications and cancellations of previously issued reports. The messages it specifies support the communication of partial, supplementary, final supplementary, complete and cumulative reports. Reporting modes which can be implemented using this European Prestandard include: sending a laboratory service report only when all laboratory investigation results are available; sending individual results as they become available; sending new results as part of a cumulative report; and sending partial results. In addition, the messages it specifies support the sending of laboratory service reports for which no laboratory service order message has been received.

This European Prestandard is not applicable to the communication of graphical or image information that forms part of a request for or result of a laboratory investigation.

This European Prestandard 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.

This European Prestandard does not support negative acknowledgment or error indication at the application level, nor positive acknowledgment at the application level.

The provisions of this European Prestandard have been validated in the domains and for the purposes described above. However messages conforming to this European Prestandard may be considered by some user communities to meet their needs for purposes outside this scope. Use of the messages in such circumstances is not precluded by the scope.

While the messages specified in this European Prestandard may convey clinical and administrative information concerning patients, the way in which this information is treated in this European Prestandard does not constrain the development of future standards for the electronic healthcare record or for other clinical and administrative messages.

5.2 User requirements and scenarios

5.2.1 Introduction

The study of the user requirements is the first major activity in the message development process. Based upon real world scenarios, the information exchange needs are identified. The main success factor for this activity is the domain knowledge available to the development team.

5.2.2 What, why

The determination of what is required by the users generates the results required for all further message development activities, which are basically only presentations of the user needs in a non-ambiguous way.

The scenario specification:

- extends the high level scenarios of the scope statement,
- gives examples of healthcare parties acting in the scenarios
- considers variances of the message exchange patterns and
- describes real world situations where the messages defined by a standard may be used.
- provides an informative overview which assists in the development of the normative components of the healthcare messaging standard.

5.2.3 Process overview

In general, the activity consists of three major steps (usually performed in parallel):

1) Requirements **gathering**: information sources to be considered for the identification of the user needs are (see Figure 6):

- the scope statement and the terms of reference;
- existing standard messages (international, national, regional, local) and standards related to the problem domain;
- existing definitions and concepts (international, national). Existing data directories should be consulted to identify whether concepts required within the problem domain have already been defined and/or used in other areas;
- systems currently used (the functionality commonly provided by systems in the problem domain);
- current information exchange patterns (of any type, e.g. paper-based, EDI-based, telephone). Ideally the information exchange patterns in use in as many countries as possible should be collected.
- a representative set of forms and of the information effectively exchanged in actual messages;
- questionnaires to key organisations, domain experts, users and providers in the problem domain may be used as a tool to collect the information as needed;
- regulatory constraints and requirements have to be taken into account;
- consideration should be given to any security/legal aspects that impact on the information content and any security mechanisms that need to be applied at the message level;
- agreed future requirements and the possibility to simplify and rationalise the communication.

2) **Selection** of those information exchange components and patterns which are definitely part of the scope or which must be considered for further elaboration;

3) **Extension/refinement** of the existing information exchange components and patterns as needed.

As the sum of the collected information will not form a consistent whole, it needs refinement. Some of the information will not be of the granularity as required for the message development activity, in which case more generic or more specific concepts may be required.

5.2.4 When

This activity must be performed immediately after the initial scope specification. Its output is required to start all other message development activities.

5.2.5 How to achieve quality

The means to ensure a high quality user requirements specification are the involvement of sufficient healthcare domain experts including those with knowledge of legal constraints, with expertise related to terminology/vocabulary, those with awareness of the state-of-the-art and common functionalities of the communicating systems involved (i.e. experts who can ensure an easy integration of the messaging functionality in existing systems).

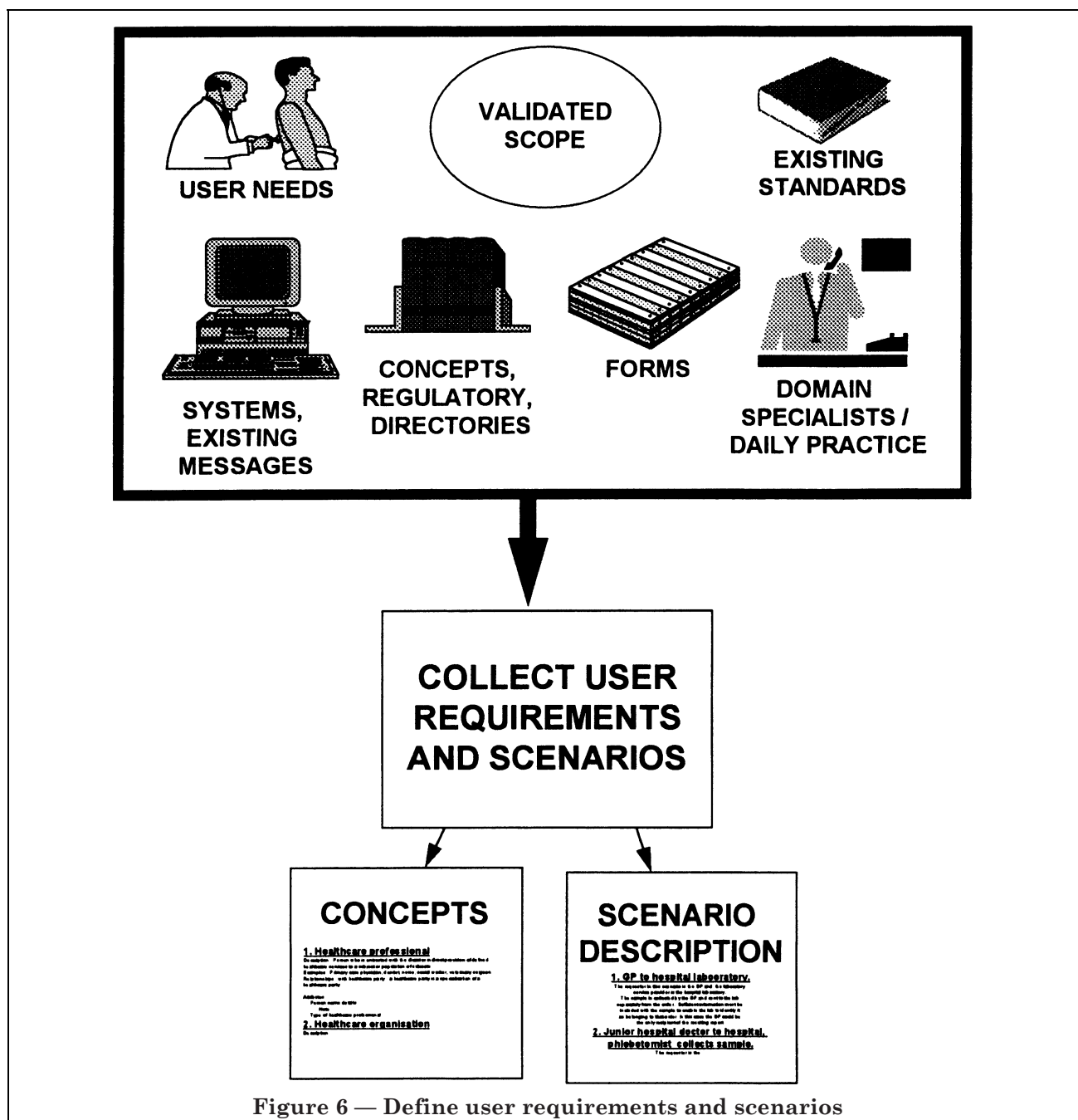


Figure 6 — Define user requirements and scenarios

5.2.6 User requirements and scenarios: summary

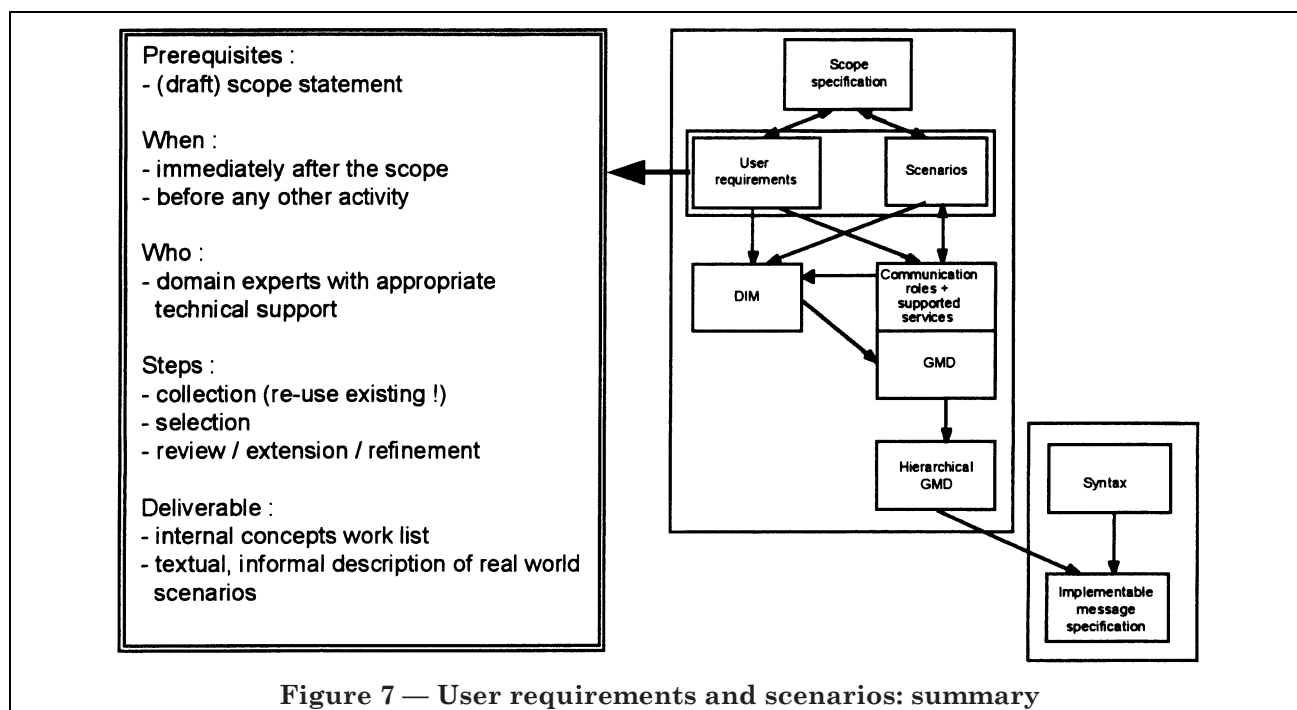


Figure 7 — User requirements and scenarios: summary

5.2.7 Scenarios: example

The following is an example of a textual specification of scenarios. The italic representation is used to stress the illustrative nature of the text.

Examples of scenarios where the new laboratory service order message can be used.

General practitioner (GP) to hospital laboratory

The requester in this scenario is the GP and the laboratory service provider is the hospital laboratory. The sample is collected by the GP and sent to the lab separately from the order. Sufficient information must be included with the sample to enable the lab to identify it as belonging to that order. In this case the GP could be the only recipient of the report.

Junior hospital doctor to hospital laboratory, phlebotomist collects sample

The requester is the junior hospital doctor and the laboratory service provider is the hospital laboratory. The hospital consultant in charge of the patient is the supervising healthcare professional. If he is to receive his own copy of the report he will be identified as requiring this in the order. Otherwise the junior doctor will be the only report recipient.

In this case the sample is not sent at the same time as the order; instructions are included in the order as to what sample is required from this patient and details of when it should be collected, the location of the patient and specific instructions as to preservation, transport requirements, handling etc. The laboratory will then arrange for the sample to be collected.

Hospital consultant in outpatient clinic to hospital laboratory

The consultant is the requester and would collect the sample. Reports would be requested for the consultant and the patient's GP. It would be specified that the report must be available in time for the patient's next outpatient attendance.

Clinician in Accident and Emergency department to hospital laboratory

In this case the clinician may not want to see the report and it would only be issued to the GP. The sample would be collected by the clinician.

Clinician in hospital to external laboratory

The clinician would send the order and the sample to the external laboratory and receive a report back.

Environmental scientist to non-hospital laboratory

The environmental scientist may send multiple samples of swimming pool water from the same swimming pool on one order. He would expect to receive all the results on one report.

Clinician requesting glucose tolerance test from hospital laboratory, phlebotomist collects samples

The clinician would issue one order and the laboratory would organize the pretreatment (glucose loading) and the collection of the samples at the prescribed intervals. The number of samples and the collection intervals may be pre-agreed between the clinician and the laboratory or specified in the order.

etc...

5.3 Communication roles and supported services

5.3.1 Introduction

The specification of the communication roles and the supported services is the key component related to the identification of the users of a healthcare EDI standard and to the possibility to validate, at a general functional level, the conformance to the standard specifications. It also includes the identification of the GMDs required.

5.3.2 What, why

The communication roles and supported services specification is used to:

- identify the healthcare parties implied by the messaging standard through the communication roles,
- define, in a generic way, the business scenarios supported by the standard through a number of message exchange rules,
- identify, at a high level, the messages for which the standard gives contents specifications and the association between the communication roles and these messages,
- validate applications for compliance against a given communication role.

The communication rules and supported services specification shall contain at least the following components:

- the identification of the communication roles implied by the standard (completed with examples as required).
- the relationship between each communication role and the GMDs defined by the standard.
- the services to be supported by each communication role in relationship with its associated GMDs.
- sequencing rules between the GMDs, if any apply within the problem domain.

5.3.3 Process overview

The main input to the process is the textual scenario specification (see Figure 8). The components of the scenario descriptions are formalised through a **generalisation and abstraction** process:

- of the healthcare parties to the communication roles,
- of the information exchange patterns to the GMDs required,
- of the textual interchange descriptions of the scenarios to a formal specification of the association between the communication roles and the GMDs and to the definition of the required external behaviour of each communication role.

Analysis of the information which is required to be collected and managed in order to support healthcare suggests that the totality of information required is very similar in all European states. In each of these healthcare systems there is also a similarity in the roles that are required to be fulfilled in order to maintain healthcare delivery systems. Much the same information in total needs to be exchanged between these roles. However the great variation in the legal (e.g. related to provision of services, financing, data protection, product safety), regulatory, funding and organisational structures at national and local levels within which healthcare operates in European states has a significant impact on the pattern of information exchanges and the potential application of EDI. In some instances the responsibilities for two roles may reside within one organisational unit with a shared information system and a shared database and thus there is no requirement for a messaging activity between the two roles. In other instances the sequence in which messages are sent may vary depending on the manner in which healthcare is financed or organised. An example of this would be the timing of sending patient identification details to a healthcare insurance/purchasing agency depending on whether the information was also used for treatment authorisation purposes as well as for updating a patient register.

This variation in the sequencing and pattern of information interchange suggests that the approach to the message standardisation effort at the international level should not seek the identification of a standard or preferred business cycle. The focus should be on fully capturing from users the information requirement and business purpose for all the individual messages including the locally applicable message cycle within the H-EDI domain under review.

The GMD-specification includes the business purposes for which the message is intended. The responsibilities of the sender and receiver are limited to those of accepting responsibility for sending and receiving. All other responsibilities which either party wishes to impose on the other, including any expected behaviour at the application services supported level, should be the subject of a separate Interchange Agreement to which the parties agree to be bound. Application level or other system supported services should not be included in the EDI message standard specification. The only services to be included are the services related to the external behaviour of the communication role.

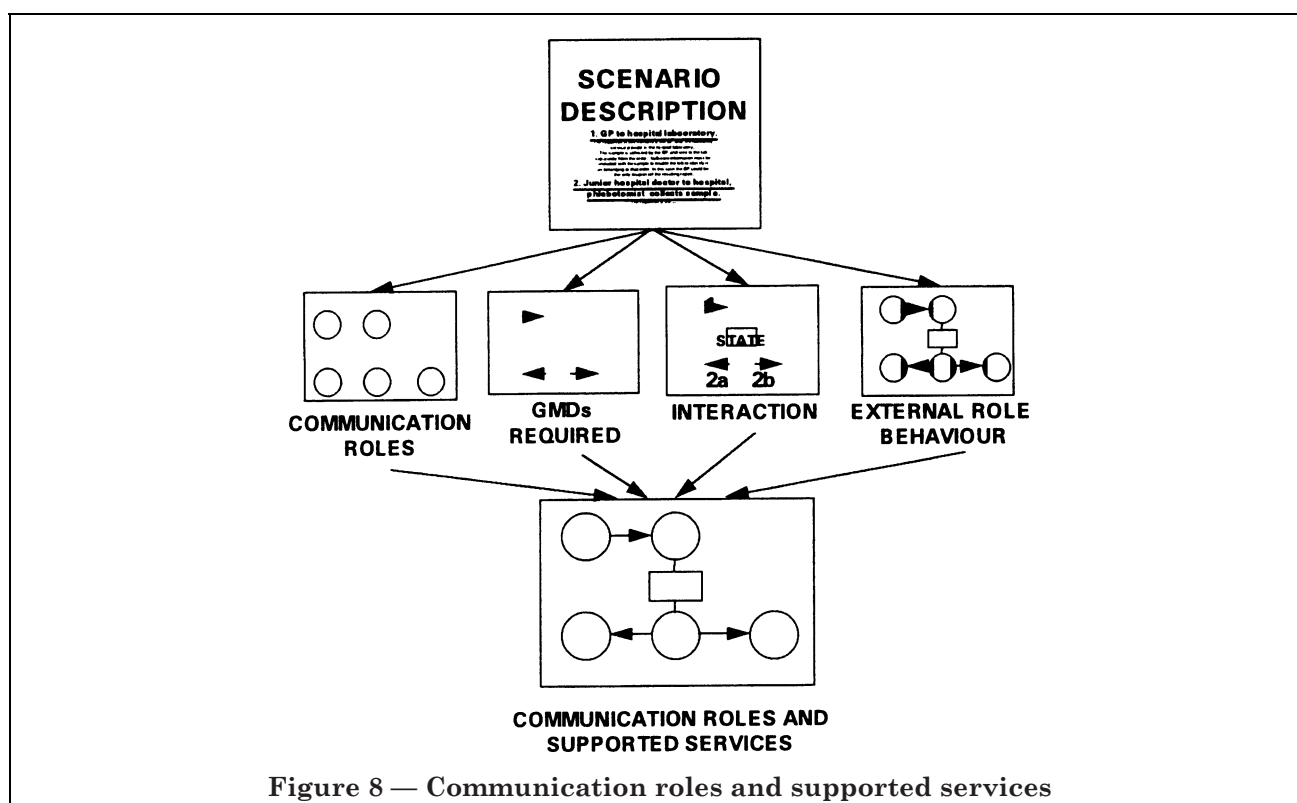


Figure 8 — Communication roles and supported services

5.3.3.1 Communication roles

These are derived from the specific types of parties with an active information exchange role in the healthcare scenario descriptions.

For each message or message group (i.e. a logically coherent or related set of messages, e.g. a new service request, a service request modification and a cancellation of a service request), the major actors which participate in the communication are called the communication parties. These should be described by their roles related to the information exchange.

Example: a general practitioner and a junior doctor in a hospital may be considered as two different healthcare party types in the scenario descriptions, but in those cases where their messaging requirements in a given domain are equal, they will be generalised into the same, single, communication role.

The variety of healthcare organisational structures across the European countries does not always allow for a simple naming of the communication parties and roles (cf. "clinical laboratory" for the standard on the exchange of clinical laboratory request and report messages).

It may be helpful to consider a name related to the function of the message, rather than a name in relation with the party. Example: instead of “clinical laboratory” (which is a party), use “laboratory service provider” or “laboratory service requester” (which are roles). The specific healthcare parties which may take up a certain role in a given country can then be considered at the level of country specific implementation guidelines.

This approach enables a broad application domain for a single standard. As the standard and the requirements are not expressed in terms of specific healthcare parties, it may be used by any healthcare party which takes up the role as defined by the standard. This approach enables the definition of standardised messages, independently on the underlying healthcare organisation structure.

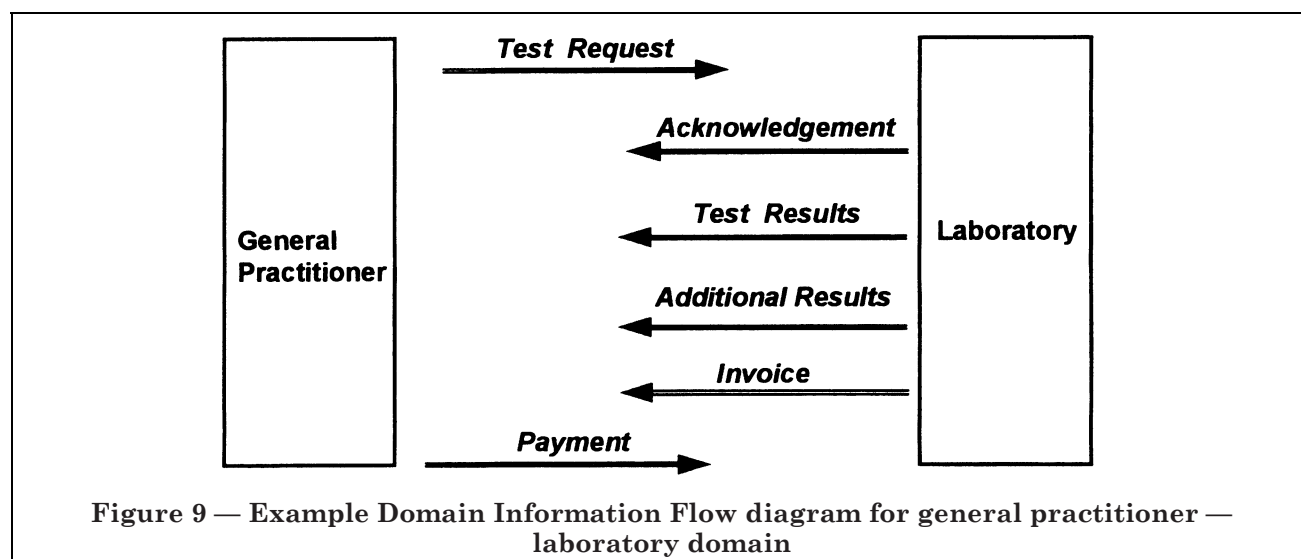
5.3.3.2 *The relationship between communication roles and GMDs defined*

For each message (GMD) chosen for development, an initial set of communication party roles should be identified.

This may be done by drawing a Domain Information Flow diagram. Its purpose is to associate the sending and receiving role with each message. The model shows the business parties (e.g. the set of business activities described as the “Laboratory” or “General Practitioner”). These sets of business activities can also be characterised as discrete “Management Domains” or “Information Domains” which have the responsibility for receiving or sending messages.

The Domain Information Flow diagram shows the information flows and their direction which are required to support the business process. It should show the sequence and implied dependencies and relationships between the information flows (e.g. this message is a response to another specified message in a business cycle, such as a laboratory test request and associated result). This should also include any requirement for acknowledgement messages etc.

A separate information flow should be identified for each distinct business purpose even though the information content may be similar.



A GMD is specified to meet the information exchange requirements of one or more of these information flows between communicating party roles. As a general rule one GMD would relate to one business function represented by one information flow. There may be instances where a GMD can meet the information exchange requirements of two information flows without a significant increase in the complexity of the GMD, although this is likely to be the exceptional case. It is more likely that there will be more than one GMD per information flow where there are significant variations in the nature and complexity of information requirements reflected in one information flow (e.g. a “simple” test result as opposed to a “complex” test result).

Not all the information flows identified will be appropriate candidates for development of EDI messages.

5.3.3.3 *The General Message Descriptions required*

The GMDs required are derived based upon a generalisation and abstraction of the functionality of the information exchanges defined in the scenarios.

Only messages at the level of the exchange of healthcare related information need to be considered (i.e. messages dealing with problems at the physical communication level should not be dealt with).

GMDs should be developed, together with supporting models, for each message for which it is proposed to develop following analysis of the detailed information flows.

A balance has to be struck between the wish to avoid developing (and maintaining) an excessively high number of GMDs and the need, where possible, to avoid introducing complexities into a message standard which are not required by many potential users. A number of criteria can be used to combine information exchange requirements to be described in one GMD. These combinations may relate to:

- information requirements originating from different sub-specialties (e.g. microbiology and clinical chemistry in the clinical laboratory domain),
- the requirements needed to cover specific, specialised cases within one subdomain (e.g. the specific information related to animals),
- the diverging granularity and specificity of the information that can be provided by “average” applications or by “state of the art” applications.

The resulting GMD may, in the end and in its full functionality, become very complex to implement (both for sending and receiving applications), whilst a GMD which is able to adequately meet the typical average information exchange needs in a particular domain may be very simple to implement.

The message developer has to use judgement rather than following any rigid rules in making decisions relating to the choice of the scope of the business functionality of a proposed GMD. One option is to develop a single GMD to cover the requirements of two or more information flows within the same or related business domains where there is a high level of commonality of information content. If this approach is adopted the GMD would contain a high level of optional information content. User communities would then select **profiles** of the information content within the message when implementing the message to meet the needs of the particular information flows in their business cycle. A consequence of this approach is that the messages may be structurally complex and impose significant demands on implementation software. There is also a close correspondence between the complexity of the GMD, the related message and the volume and complexity of supporting documentation that has to be assimilated by prospective users and software application developers.

The alternative approach is to develop a larger number of GMDs such that a separate message is produced for each commonly occurring pattern of information. This may result in more than one GMD being produced for each information flow identified in the Domain Information Flow diagram. The benefit of this approach is that the complexity (and often the simplicity) of messages and the supporting documentation can be more readily matched to the level of complexity or sophistication of the business requirement which the user or software developer is addressing.

In order to assist in making the judgement on the number of GMDs that are required, scenario descriptions should be analysed. The objective is to identify commonly occurring patterns of information that are exchanged as an information flow to meet a particular level of business transaction in the domain under review. It is the individual patterns of information exchange which will reflect actual user experience and perceived requirements. At this stage it is important to recognise and document those business requirements where there are in practice several commonly occurring but distinctive profiles of information content for a single information flow. It is important that the potential users of the messages define as far as possible the different patterns of information exchange which reflect differing levels of complexity, granularity and richness of meaning which are required to be exchanged within what is ostensible the same type of information flow. For example there is likely to be a pattern of information related to a “basic” or limited functionality laboratory report. There is likely to be another common pattern of information exchange related to laboratory reports where a richer level of information is required.

These patterns of information exchange may also be influenced by the information technology architecture environment within which users operate. Users may wish to specify a very limited data content for messages designed to constitute dialogues between parties to achieve a particular business objective in an interactive EDI environment.

It is these familiar patterns of information which the users will wish to be able to readily recognise in any supporting documentation and models when an implementable message specification is presented to them for approval and subsequent use. Careful consideration should be given to the merits of developing a GMD for each “pattern” of information exchange usage that is commonly found in the user domain.

5.3.3.4 External role behaviour

The messages are exchanged to satisfy a given purpose. In order to guarantee that the message purpose can be fulfilled, a limited set of services must be imposed on each of the communication roles. These services relate to the ability to send or receive EDI messages in conformance with the standard specifications and the ability to send/receive these messages according to minimal sequencing rules.

The external role behaviour specification links together the communication roles, the GMDs and the relationships (if any) between GMDs.

5.3.4 When

- The first identification of the communication roles and of the GMDs required is usually done by the scope statement.
- Once scenario descriptions (part of the user requirements) are available a more precise specification of the communication roles and of the GMDs required can be made.
- The relationships between GMDs and external role behaviour can be described once the communication roles and the GMDs required are stable.
- The scenario specification is ideally reviewed and reorganised after this activity to show the relationships between the formal specifications and the textual descriptions clearly.

5.3.5 Representation

Graphical support is recommended to show the associations between the communication parties and the GMDs, and (if any) to show the sequencing rules for the GMDs defined by the standard.

5.3.6 Quality requirements

- 1) Completeness:
 - all communication roles associated with GMDs covered by the standard shall be identified.
 - each GMD shall be associated with both a sending and a receiving communication role.
 - for each association between a GMD and a communication role, the services to be supported shall be defined.
 - the relationships between GMDs shall be specified if any apply to the problem domain.
- 2) The names of the GMDs required shall be consistent with the names of the GMDs which are defined by the messaging standard.
- 3) The communication roles shall be clearly associated with a specific or a generic healthcare party.

5.3.7 Communication roles & supported services: summary

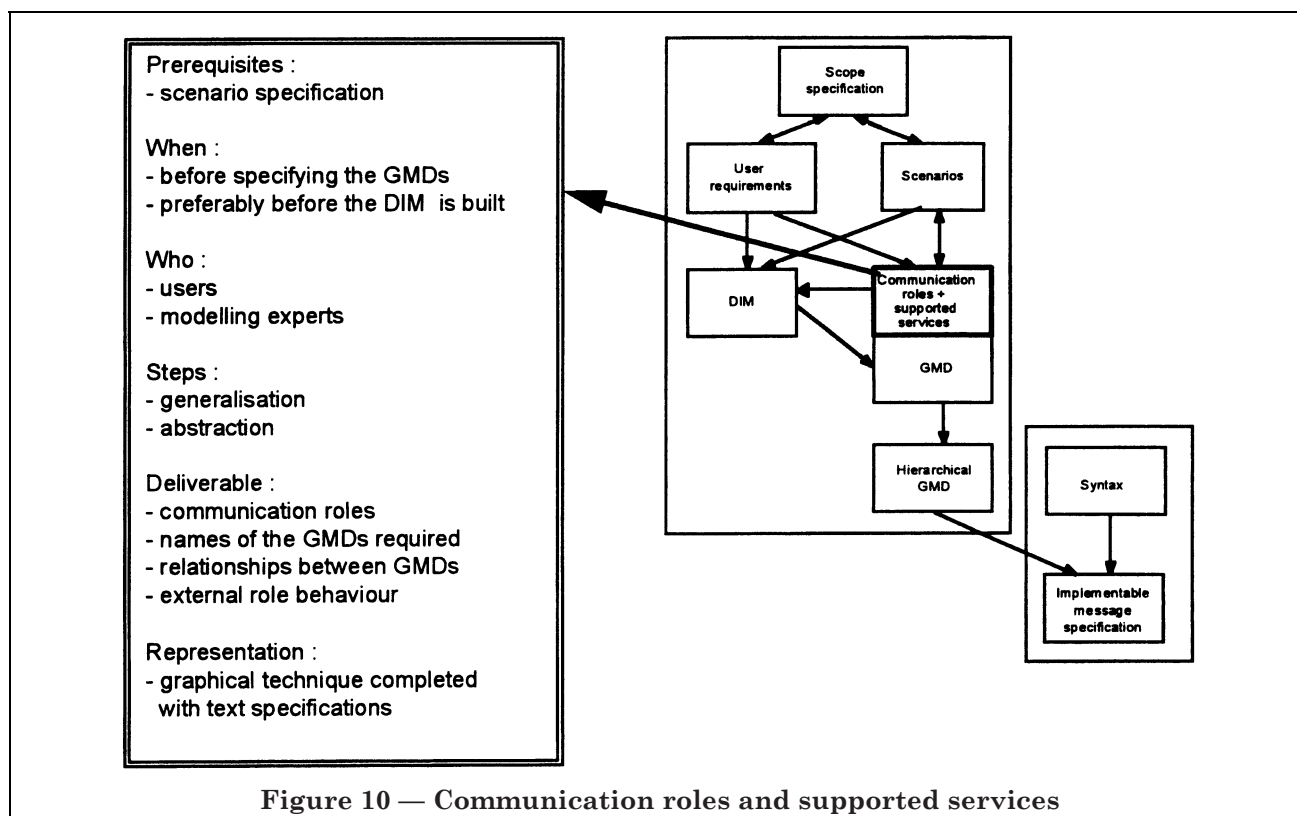


Figure 10 — Communication roles and supported services

5.3.8 Example:

Communication roles

Four types of communication roles can use the messages based upon the GMDs:

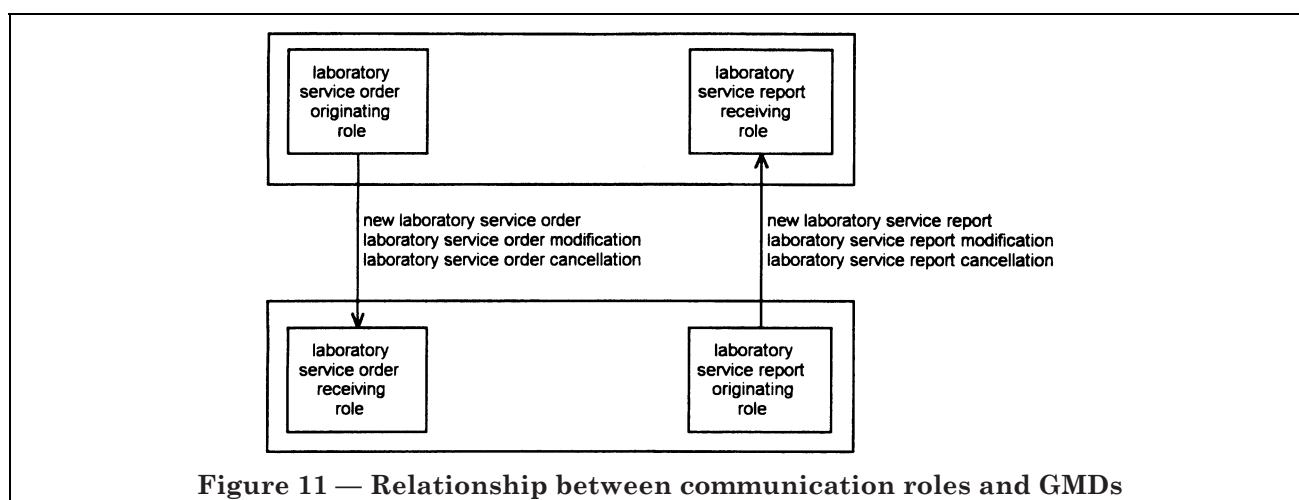
- laboratory service order originating roles,
- laboratory service order receiving roles,
- laboratory service report originating roles,
- laboratory service report receiving roles.

A single healthcare party may have one, two or more of the above mentioned roles.

EXAMPLE: a general practitioner may have a laboratory service order originating role and a laboratory service report receiving role.

Communication roles and General Message Descriptions

The relationships between the communication roles and the message types for which this standard provides General Message Descriptions are expressed by the Figure 11.



Communication roles and supported services

The services that shall be supported by a communication party with a laboratory service order originating role are:

- issue new laboratory service order message instances which comply with the new laboratory service order General Message Description and which convey in a complete and exact way the information as intended by the sender and as to be understood by the receiver,
- issue laboratory service order modification message instances which comply with the laboratory service order modification General Message Description and which convey in a complete and exact way the information as intended by the sender and as to be understood by the receiver,
- issue laboratory service order cancellation message instances which comply with the laboratory service order cancellation General Message Description and which convey in a complete and exact way the information as intended by the sender and as to be understood by the receiver,
- issue these message instances in accordance with the messaging sequencing rules for laboratory service order message originating roles.

etc...

5.4 Build Domain Information Model

5.4.1 Introduction

The Domain Information Model is the model representing the things in the domain about which information may be exchanged between the communication rules. Its purpose is to represent the overall information dimension of the user requirements for the healthcare exchange domain under consideration. All GMDs are, by definition, subsets of the DIM, as the DIM acts as a reference model for the GMDs. It may however include and define more information than needed for the GMDs alone. This allows, up to a certain degree, the development of supplementary GMDs based upon the same DIM.

5.4.2 What, why

The DIM identifies a set of real world entities present in a given healthcare information exchange domain. It shows the relationships between the entities and the information about them which is to be exchanged. It is the representation of the user requirements related to the information dimension of the problem domain. It does not consider the dynamic dimension of the information exchange requirements.

The Domain Information Model consists of the following components (terminology according to Coad/Yourdon, but these components are not dependent on the technique used for their representation):

- model diagrams, containing the following components:
 - classes and class-&-objects representing the real world entities,
 - relationships (connections) between individual classes and class-&-objects (including cardinalities)
 - subjects (i.e. references to diagrams representing -other- subjects)

- attributes belonging to classes and class-&-objects representing the data associated with the real world entities (often shown separately)
- class specifications (name, definition, notes, examples, attributes, relationships with other classes, ...)
- attribute and attribute group specifications (number of values within a given class, data type, name, definition, notes, examples)
- model notes and complementary specifications, as needed.

The complete component breakdown is included in clause **5.4.9**.

The DIM is used as:

- the central reference model for the specification of the GMDs. As such, it is a means to ensure consistency throughout the set of GMDs,
- the consolidation of the information content of the GMDs, and as such a means to define the scope of a healthcare messaging standard and to present the concepts towards the users,
- a guideline by system developers:
 - to check correspondence and divergence between their own application models and the information exchange model,
 - to analyse how to amend the applications towards interoperability with the standard.
 - to find out about the definition of a term, etc...
- by clinical user representatives to validate the standard's completeness against the medical requirements,
- etc...

5.4.3 When

The construction of the DIM can be started once a clear view on the user requirements, the communication roles and the General Message Descriptions required emerges.