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Alignment - Draft final report v0.5**

SOURCE:

David Markwell

**ACTION
REQUIRED:**

FOR DISCUSSION AT THE NEXT TC 251 MEETING 1999-12-07

CEN/TC 251 Secretariat: SIS-HSS (Swedish Healthcare Standards Institution)

Mail address: Box 704 87

SE-107 26 Stockholm, Sweden

Fax: +46(0)8 702 4915

Tel: +46(0)8 702 4916

TC Secretary:

Karin Kajbjer

Visiting and Courier mail: Hornsgatan 20

e-mail:

karin.kajbjer@hss.se

Web site:

www.cenc251.org

CEN/TC 251

CEN/TC 251 - Short Strategic Study on Message Alignment

Final Draft Report - *Author: David Markwell*

Status

This is the final report of the Short Strategic Study on Message Alignment. It was accepted by CEN TC251 WGI at its October 1999 meeting in Prague. It has had only a few minor typographical changes since the version 0.4 presented at the CEN TC251 meeting in September 1999. That report was originally delivered to the supervisor of the study (Christine Michel) and to the CEN TC251 Secretariat on 5 August 1999.

The resolutions of the October meeting of CEN TC251 WGI record that, in addition to accepting the report, the Working Group supported the recommendations contained with only minor variation in emphasis on some points. The author of this report was instructed to prepare some Work Item proposals based on some of the key recommendations and these have been delivered to CEN TC251 with this revised version of the report.

The original proposal for this study was accepted in September 1998 with the revised text of the international proposal accepted in December 1998. The author notes that this report is being delivered later than envisaged when in the proposal. This is a consequence of a time of rapid change including the completion of the most recent messaging standards and the initial activity in ISO. The first three meetings of ISO TC215 WG2 have added to the understanding of the commonalities and differences between CEN and HL7 approaches to healthcare communication. The current situation is outlined in the international perspective section of the report. Increased understanding of the relative merits of the two approaches has undoubtedly influenced other discussions, conclusions and recommendations in this report.

Document structure

The main report includes the following sections.

CEN TC251	ERROR! BOOKMARK NOT DEFINED.
CEN TC251 - SHORT STRATEGIC STUDY ON MESSAGE ALIGNMENT	3
1 INTRODUCTION	5
1.1 Background	5
1.2 International perspective	5
1.3 Outline of the topics covered in the report	6
2 FINDINGS OF THE STUDY	7
2.1 Message development method	7
2.2 Documentation style	12
2.3 Information model content	16
2.4 Management of overlapping content	21
2.5 Domain boundaries and general messages	25
2.6 Overlap with other Prestandards	28
2.7 International perspectives	29
3 SUMMARY OF RECOMMENDATIONS	32

These annexes not changed since the previous version are available in a separate file on the web server: www.cenc251.org/sss/N99-079annexes.zip

Annex A	An analysis of the structure of past and current CEN message standards.
Annex B	Simplified output from a detailed analysis of CEN TC251 classes and class naming.
Annex C	Proposals for implementation of the revised structure for representation of Healthcare Agents. This was prepared as part of this study and accepted as part of the three most recently adopted CEN message standards.
Annex D	A draft Template for drafting future message standards with annotated comments. This is intended to form the raw material for a Style Guide to support authors of message standards and increase the degree of uniformity between these documents.
Annex E	An inventory of existing non-European initiatives in healthcare messaging with cross-reference to relevant CEN TC251 message standards.
Annex F	A summary of the HL7 Version 3 Message Development Framework indicating similarity and variation between this and the CEN TC251 method.
Annex G	References to key literature relating to the specification of Data Types in the information models and messages and a comparison of the types supported by CEN TC251 with those supported by HL7 and the recommendations and definitions of ISO11179.
Annex H	An analysis that categorises the classes identified in Annex and considers how they relate to the more general record component classes specified in the EHCR Communication Prestandards (ENV13606)

1 Introduction

1.1 Background

CEN TC251 has generated four Prestandards specifying messages for different types of communication between healthcare parties and current work will add a further four Prestandards to this set. There are several variations in style and content of these Prestandards. Some of these differences are a direct result of the different business purposes served. However, other differences result from growing appreciation of the user requirements, enhancements in modelling methods and more rigorous effort to clarify implementation issues in the Prestandards.

A common style of documentation and more consistency of content would help understanding and implementation of the full range of messaging Standards. Therefore, this Short Strategic Study was commissioned to consider the variations between these documents and to propose a way forward that would lead to harmonisation of CEN TC251 message Standards.

The production of CEN TC251 message Prestandards has been carried out in three phases as shown in Table 1. In each phase there have been:

- ❖ Variation in and development of the presentational style;
- ❖ Enhancements or variations in data content and structure;
- ❖ Decisions on domain boundaries that have resulted in overlap and/or gaps in the applicability of the messages.

Table 1. Phases of CEN TC251 Message Development

Phase	Features and factors	Message Prestandards in this phase
1	Initial use of syntax independent message development method – Coad & Yourdon models	<i>ENV1613</i> Messages for exchange of laboratory information
2	Experience of ENV1613 Method description in CR12587 (Methodology for the development of healthcare messages). Introduction of Hierarchical GMDs	<i>ENV12538</i> Messages for patient referral and discharge <i>ENV12539</i> Request and report messages for diagnostic service departments <i>ENV12612</i> Messages for the exchange of healthcare administrative information
3	Further experience of use of CR12587. Changes in modelling techniques to use UML.	<i>ENV13606-4</i> EHCR Messages <i>ENV13607</i> Prescription messages <i>PT32</i> Blood transfusion messages (2 parts) <i>prEN13609-1</i> Supporting information messages - Part 1. <i>ENV13609-2</i> Supporting information messages - Part 2.

1.2 International perspective

The advent of ISO TC215 WG2 “Health Informatics – Messages and Communication” will enable a more International approach to healthcare message Standards. However, this requires European experts to have an appreciation of the similarities and differences between the approach to healthcare messaging inside and outside Europe.

The HL7, X.12 and ASTM communities in the US have undertaken the most significant healthcare messaging work outside Europe. This report includes a high-level assessment of the areas of overlap between this work and CEN activity. A more detailed comparison with HL7 Version 3 is also being prepared for inclusion in the final report.

1.3 Outline of the topics covered in the report

1.3.1 Message development method

The basis for the development of CEN TC251 messages is the method defined in CR12587. However, the method has evolved with experience without further formal documentation.

1.3.2 Variations in style

The message Prestandards developed in each phase have improved in terms of technical consistency and presentation. This is a result of progress but has inevitably caused divergence between the Prestandards.

The SSSR on Enabling Technologies recommended that all previous Prestandards should be revised to present their models using UML rather than Coad & Yourdon. While TC251 WGI accepted the recommendation of UML for current and future work the suggestion of revising models was deferred for further consideration.

1.3.3 Overlapping content

All the message Prestandards developed by CEN TC251 have some common data classes. The specifications of these are repeated in each document. ENV 12537 (Registration of information objects used for EDI in healthcare) has provided a framework for a register of data elements but as yet there is no formal registration authority.

1.3.4 Variations in content and data structure

While sharing overlapping content, there are known to be some detailed differences between the data content and structure of classes that are common to two or more Prestandards. These differences may be the result of differing domain needs, increased understanding of the general requirements in each generation of development or of errors in transposition. In some cases, the differences are confined to descriptive text that refers explicitly to a particular element that is specific to the domain or in a domain specific example.

1.3.5 Domain boundaries and general messages

The historically drawn boundaries between some of the messaging Prestandards have in some cases seemed arbitrary when considering implementation.

Experience has indicated that the current divisions result in:

- ❖ Duplication - some "simple" messages with almost identical content in several different domains (e.g. cancellation).
- ❖ Over generalisation - messages that contain features required only by a part of a domain.
- ❖ Over specialisation - messages that contain classes with similar purpose but different content.
- ❖ Exclusion of some general-purpose messages from the scopes of all the domains (e.g. acknowledgements).

1.3.6 Overlap with other Prestandards

ENV12018 (Identification, administrative, and common clinical data structure for Intermittently Connected Devices used in healthcare – including machine-readable cards) produced by the former CEN TC251 WG7 contains many elements present in messaging Prestandards. However, these are presented in a different format.

2 Findings of the study

2.1 Message development method

2.1.1 Methods for development

The two most developed methods for developing message standard in healthcare are the CEN TC251 method (based on ENV12587) and the HL7 Version 3 Message Development Framework. The principle differences between the current CEN method and the methods used in the MDF are summarised in Table 2. This table is an abbreviated summary of a more detailed comparison in Annex F ([MsgAlign-F-04-DevelopmentMethods.doc](#)).

Table 2. Summary of message development in CEN TC251 and HL7 Version 3

Process	CEN TC251 Method	HL7 V3 MDF
Requirements analysis	<p><i>Communicating parties</i> identified.</p> <p><i>Communication requirements</i> specified informally.</p> <p><i>Scenarios</i> (now with UML sequence diagrams).</p>	Use case analysis with formal modelling
Information analysis	<p><i>Domain Information Model</i></p> <ul style="list-style-type: none"> ❖ This represents a particular domain ❖ There is no overall reference model but an increasing move to share common classes or subclasses. ❖ The DIM is presented in UML using hand crafted diagrams or CIC message modelling tool (developed for CEN use by the author of this report using the ENV12537 data structure with many enhancements. Freely available to CEN TC251 though not well documented or supported) 	<p><i>Reference Information Model (RIM)</i></p> <ul style="list-style-type: none"> ❖ This represents sum of all covered messaging domains. ❖ This overall model is maintained separately from individual domain developments. Requirements for change arising in a domain are submitted for consideration by a formally constituted task force. ❖ The RIM is presented in UML language using Rational Rose. Rose is a commercial, fully supported product with a relatively high price tag. It includes some features not used by HL7. Some additional style rules are specified in the HL7 MDF to deal with aspects not covered directly by Rose.
Interaction design	Not done in any formal way.	<i>Interaction Model</i>
Message design	<i>General Message Description</i> and <i>Hierarchical Generalised Message Description</i>	<i>Hierarchical Message Description</i>
Message specification	<p><i>Implementable Message Specification</i></p> <p>Considered outside scope of CEN TC251 activity until now. However:</p> <ul style="list-style-type: none"> ❖ Most published Prestandards include examples in either EDIFACT or XML so far. ❖ Rules for mapping to XML being developed but outside formal WGI scope. 	<p><i>Implementation Technology Specification</i></p> <ul style="list-style-type: none"> ❖ Actual or potential specific guidance for syntaxes including: HL7, CORBA, OLE, SGML, XML and EDIFACT.

The basis for the development of CEN TC251 messages is the method defined in CR12587. This method arose from the experience of working on the development of ENV1613. It has been found to be useful and also forms the basis for the Message Development Framework used by HL7 for development of HL7 Version 3.

Extensions and variations to the method have been made based on experience in subsequent rounds of message development. Most of the changes are changes in presentational style rather than fundamental shifts in the method. There has been no formal effort to document these variations in a revised version of CR12587.

However the HL7 version 3 Message Development Framework includes various extensions to and enhancements of the method used in the HL7 community. The advent of ISO TC215 is increasing co-operation between CEN messaging experts and HL7 with a proposal for a common ISO Standard for a Healthcare Message Development Method. CEN experts are currently reviewing the HL7 MDF as a potential basis for this global standardisation effort.

2.1.2 Impact of the methods on the alignment of deliverables

The message development method affects many other aspects of message alignment.

- ❖ Differences in methods usually result in differences in documentation style.
 - The content of each clause of a standard is a product of one or more of the stages in the development method.
 - The absence of a step in the method implies the absence of any content that might have been delivered by that step.
 - However, inclusion of a step in the method need not imply inclusion of content. Some steps may generate material used in subsequent steps but not required by users of the eventual standard.
 - The method may explicitly specify the documentation style in respect of some or all of the clauses of the delivered standards.
- ❖ Different methods may place more or less emphasis on a harmonised set of common classes shared between standards.
 - The HL7 Version 3 MDF includes detailed procedures for deriving new messages from and maintaining a common Reference Information Model (RIM). Work in individual domains starts with a copy of the RIM and proposes changes to that RIM. The proposed changes are then formally resolved to generate a revised RIM capable of meeting the needs of each domain without compromising the requirements of existing domains.
 - CEN TC251 does not have a Reference Information Model but emphasis is placed on reuse of classes where deemed appropriate. Thus the process is much less formal. This study found a stepwise increase in the differences between each round of standards with no planned activity to align the earlier work with newer enhancements.
 - Recent EHCR development in CEN TC251 do provide more generic constructs that may form a basis for a Reference Information Model based on the EHCR Architecture. This appears more flexible than the current HL7 RIM - particularly in the area of clinical information. However, a formal method for using, developing and maintaining this is required if it is to be effective as a backbone for revised and new message standards.

- ❖ Boundaries between domains may be identified in different ways that are predicated by the development method.
 - The CEN TC251 method involves the time limited assignment of work item to a task force or Project Team. The scope of each work item has been determined before detailed study of boundary issues and the requirement to create a discrete package of responsibilities tends to create overlap and gaps. Thus the team responsible for "laboratory requests and reports" avoided some generic requirements (e.g. acknowledgement messages), which left gaps and included others (e.g. cancellation messages), which created overlaps.
 - The HL7 MDF allocates "stewardship" for an area of the RIM to particular groups of people. These responsibilities continue over time rather than being delimited by particular a delivery date. Boundary areas where gaps or overlaps may develop can be addressed by discussion between the stewards. There is no need for each group to define specific solutions for requirements.

2.1.3 Conclusions from the comparison of methods

There are three main areas in which comparison between the CEN TC251 and the HL7 Version 3 approach reveals opportunities for significant improvement in the CEN TC251 method. These are:

- ❖ The Reference Information Model and its associated procedures;
- ❖ The Interaction Model;
- ❖ The Common Element Type Definition.

Each of these is discussed in the following section.

2.1.3.1 *The Reference Information Model and its associated procedures*

The CEN TC251 method lacks a formal mechanism for linking emerging information models to one another to achieve consistency between domains and over a period of time. The HL7 Version 3 approach may be effective but it should be noted that as yet no Version 3 messages have been implemented. Therefore, the real-world interplay between actual implementations and revisions arising from harmonisation activities may well require modification of that procedure. However, observations made elsewhere in this study indicate that the problems of divergence in the message descriptions for different domains are real and significant. Therefore, the future effectiveness of CEN TC251 message standards is likely to depend on some form of Reference Information Model. In this respect the options include:

- a) Creating and maintaining a CENTC251 RIM based on current published message Prestandards and the EHCR Architecture Prestandards;
- b) Co-operating with HL7 to develop an International RIM (probably within the context of ISO),
- c) Utilising a more general semantic repository (such as the BSR) and populating this with the relevant components for a healthcare RIM.

All of these options have continuing resource implications which would not be directly associated with delivering a particular Standard or Prestandard.

Recommendation 1 CEN TC251 should consider the options for rationalising and maintaining alignment of future message content by developing and maintaining or participating in the development and maintenance of a healthcare message Reference Information Model.

2.1.3.2 *The Interaction Model*

A significant difficulty in respect of past CEN TC251 message standards has been the question of specifying and testing conformance. Therefore, while the standards specify the information content they do not specify the particular responsibilities of sending and receiving systems.

The HL7 Interaction Model addresses this issue. It identifies interactions that involve communication and for each of these interactions specifies the following properties:

- ❖ **Interaction Name & Identifier**
- ❖ **Receiving Application Role:** The application role responsible for receiving the message involved in this interaction. The receiving role must be able to accept the message and to fulfil the receiver responsibility.
- ❖ **Sending Application Role:** The application role responsible for recognising the trigger event and causing the appropriate message to be sent.
- ❖ **Initiating Trigger Event:** The trigger event that triggers or initiates this interaction.
- ❖ **Message Transferred:** The identifier of the message format for the message that the interaction transfers.
- ❖ **Receiver Responsibility:** Definition of a follow-on interaction that the receiver must initiate. This is optional as there may be no follow-on responsibility.

This provides the background for specification of conformance criteria.

Recommendation 2 CEN TC251 should extend the deliverables of CEN message standards to include a specification of the interactions that result in the exchange of particular message types. Following a similar approach to the HL7 Version 3 Interaction Model each interaction should be specified in relation to the roles and responsibilities of sending and receiving applications and the message exchanged between them.

2.1.3.3 *Common Element Type Definitions*

The Common Element Type Definition (CETD) of HL7 Version 3 is quite different from the common classes used in CEN TC251 messages. A CETD defines a subset of a more general class, which can be used in several messages. Thus the general class person may be present in full in some messages but in other messages may require only a limited subset of the content of that class (e.g. an identifier).

The CEN TC251 approach to this issue has been the use of large numbers of optional attributes, resulting in reliance on implementation guidelines. However, in the recently published ENV13606-4, a similar problem was dealt with by specifying specialisations with enhanced more specific constraints on some attributes inherited from the generalisation.

Another related issue, which has been more significant in the European context, dealt with by CEN than in the HL7 community is the requirement for profiles that meet national needs.

A mechanism that enables refinement of common building blocks by increasing constraints (including reducing a multiplicity to zero - i.e.: not used) for use of the same class in different contexts. This mechanism should allow refinement in both:

- ❖ the standard message (when certain attributes or options are never needed in a particular message)
- ❖ national or local profiles of a message (when certain attributes or options are not needed when particular message is used in a particular national or local environment).

In the some CEN TC251 messages, domain restriction have led to definition of some classes, with general sounding names, but with a limited set of attributes specific to use in that domain. Increasing the scope of these classes, as part of a migration towards a common Reference Information Model, will increase the need for a mechanism that enables refinement of such classes for use in a particular context.

Recommendation 3 CEN TC251 should consider defining mechanisms for enabling (and where appropriate restricting) profiling of classes in ways that retain their connection to the underlying model while reducing complexity and redundancy in messages.

2.2 Documentation style

2.2.1 Modelling approaches

The move to UML has been agreed by CEN TC251 WGI based on the recommendations of the Short Strategic Study on Enabling Technologies. It has been adopted in all the current work items of CEN TC251 WGI.

From the perspective of message alignment the issue is whether to update existing Prestandards to utilise UML. The use of different modelling techniques is a significant distraction to readers and implementers but UML is only one aspect of a wider set of stylistic issues. Therefore, it would be unhelpful to simply represent the Domain Information Models and Generalised Message Descriptions in UML without also making other changes to style.

Recommendation 4 CEN TC251 should instruct authors of future and revised message standards that all model diagrams should be presented using the subset of UML, diagrammatic style and tabular representations of the class descriptions used in ENV13606-4, ENV13607 and ENV13609-2.

2.2.2 Document structure

Annex A ([MsgAlign-A-04-DocStructures.doc](#)) contains an analysis of document structure of current CEN TC251 messaging Prestandards. This analysis highlights a variety of differences in the ordering and naming of sections and figures in these documents.

Some of these variations are an inevitable result of evolution of the method but some seem to indicate a lack of discipline within the teams of authors. In practice, some of the differences may result from dissatisfaction with particular phraseology or changes in response to comments received by the authors during the development process. Nevertheless, it is clearly a distraction for readers to find similar elements of the document in different places or with different names.

Recommendation 5 CEN TC251 should instruct authors of future and revised message standards to adopt a common document structure and to follow common conventions for naming sections and figures within the document.

2.2.3 Document size

Those involved in the development of healthcare message standards receive frequent comments about the size and complexity of the documents delivered. It is self-evident that size is neither a measure of quality nor an inherent weakness. The documents need to be of sufficient size to convey the requirements in a clear and precise manner. Reductions in size at the expense of clarity are not acceptable. However, consideration should be given to ways of reducing size while retaining clarity.

The most obvious opportunity for reduction is the repetition of elements applicable to more than one message. Two aspects of this are considered in subsequent sections of the report:

- a) A single register or Standard defining common elements and data types would reduce most of the documents by between 10 and 20 pages.
- b) Redefinition of scope boundaries to allow use of generic messages for some common purposes would effect a further significant reduction to request and report messages.

Another area in which the current Standards vary considerably is the inclusion of material used during the development process, which is not strictly necessary for implementation of the messages. In particular, WGI has discussed the status of the original network style of

General Message Description. This form is intermediate between the Domain Information Model and the final Hierarchical General Message Descriptions and is important to the authors of the standard but of questionable value to message implementers. The last time this matter was discussed, it was agreed that this material should either be omitted or included as an informative annex. This has left the decision in the hands of the authors or individual message standards resulting in lack of uniformity in approach.

Recommendation 6 CEN TC251 should instruct the authors of all future and revised message standards to exclude network presentations of GMDs from the published standards. This does not preclude this and other developmental material being made available in electronic forms as additional supporting material.

2.2.4 Typographical conventions

Another area of variation between the style of current documents concerns the use of typographical conventions. In particular:

- ❖ Some documents capitalise the initial letter of each word in a class or attribute name while others use lower case only.
- ❖ Some documents rigorously use italicised text to refer to class or attribute names within the text while others do not.

It would be useful to enforce a standard convention. However, neither capitalising or italicising results in a clear and unambiguous delimitation of class and attribute names. Particular problems arise with classes or attributes, whose names differ only in the presence or absence of a prefixing word. Such instances are not always obvious due to breaking across lines or grammatical requirements for capitalisation of words that are not part of the name. This is related to the more general issue regarding naming of classes and attributes (see 2.2.5).

2.2.5 Attribute and class naming conventions

The analysis of classes in existing message Prestandards shows wide divergence resulting from a failure to establish formal naming conventions at an early stage in the development process. A comparison with HL7 version 3 suggests that applying more formal technical naming rules can lead to a clearer distinction between text describing a real world concept and its technical representation as a class or attribute.

Descriptive free-text naming of classes and attributes in CEN TC251 messages has resulted in:

- ❖ Some long and unwieldy attribute names,
 - eg: "additional execution instruction of standing requested laboratory investigation"
- ❖ Different lexical styles applied to similar or related classes or attributes,
 - eg: contrast the following
 - "association description between subjects of investigation"
 - "relationship type of related person"
 - "healthcare agent relationship type"
- ❖ Lack of clarity in the distinction between references to a class or attribute and references to the real world concept with a similar name.
 - "The attribute *additional execution instruction of standing requested laboratory investigation* contains information about an additional instruction connected with a standing order for a laboratory investigation."

The following conventions are suggested to provide greater consistency and clarity in class and attribute naming.

- a) The names of classes and attributes shall not contain spaces. Any spaces should be replaced by underscore characters "_".
- b) The initial letters of a class or attribute name shall not be capitalised.
- c) The name of an attribute shall not include the name of the containing class.
- d) When referring to a class or attribute from within a textual description, the name of the attribute shall be italicised. Italics shall not be used when the name of a class or attribute is used in a heading or caption. In information model diagrams the name of a class shall be italics only if that class is an abstract class.
- e) When referring to an attribute in a specific class where the name of the class is not clear from the surrounding context the name of the attribute may be prefixed with the name of the containing class. In this case the name of the class shall be separated from the name of the attribute by a single full stop.

Example:

The class *standing_order* might contain instances of the class *requested_investigation*. The *requested_investigation* class might contain one or more instances of the attribute *additional_execution_instruction*. To refer unequivocally to this attribute the form *standing_order.requested_investigation.additional_execution_instruction* may be used. However, usually it will be sufficient to refer to *additional_execution_instruction*.

Recommendation 7 CEN TC251 should adopt formal conventions for class and attribute naming and for the typography of references to classes and attributes in the text of the standard. The nature of these rules is suggested in 2.2.5.

2.2.6 Impact of PNE rules and ISO directives

The rules for drafting of standards in CEN and ISO have at times appeared burdensome to the development of clear representations. The decision to move from PNE rules to ISO directives is welcome as it will pave the way for easier migration of future message standards between ISO and CEN.

There is a clear distinction between adopting the ISO conventions and using the ISO templates for drafting Standards. Those who attempted to use this have found them positively unhelpful. This is probably because they were designed with rather simpler textual structures in mind.

*Recommendation 8 CEN TC251 should instruct authors of future and revised message standards to follow ISO directives but should advise them **not** to use the ISO templates for this purpose.*

2.2.7 Adopting a style guide

Taking account of the individual points made above, there is an urgent requirement to create a formal style guide for the delivery of communication standards. This should act as the final arbiter on the style and presentation of these standards.

The guide should cover:

- ❖ Order and content of clauses;
- ❖ Naming of clauses, sub-clauses and figures;
- ❖ Naming conventions applied to classes and attributes;
- ❖ Presentation of Hierarchical GMD diagrams;
- ❖ Presentation of DIM top level and package diagrams;
- ❖ Presentational style adopted for attributes;

- ❖ Representation of relationship between specific message standards and common elements in registries or referenced standards;
- ❖ How relationships are represented in textual descriptions

A template with annotated comments is included as a starting point for definition of a style guide for future message standards (see Annex D - [MsgAlign-D-04-StyleGuide.doc](#))

Recommendation 9 CEN TC251 should instruct WGI to develop and adopt a style guide for future message standards. This should be accompanied by an example document including a single example of each of the styles, figures and table formats specified. The starting point for this should be the draft provided as Annex D to this report.

2.2.8 Revising existing documents in line with a style guide

The main reasons for moving to a more consistent approach are:

- ❖ The use of a common modelling method and appropriate sets of tools will aid consistent mapping into implementable syntaxes.
- ❖ Domain boundaries (see 2.5) are not rigid. Implementers and testers need to study and apply a set of message standards together, rather than as isolated products.
- ❖ Common presentation to facilitate consistent understanding and implementation.

The main reservations about doing this are:

- ❖ The effort required for this update.
 - This should be reduced by combining the change with other updates and by using common elements and tools used for development or current messages and for undertaking the content comparison (see 2.3.4).
- ❖ The need to combine this with other updates in the formal review of these document so that this is not simply a cosmetic change.
 - The current SSS on the Laboratory message should provide an initial test case for the feasibility of this.
- ❖ Potential future methodological changes that may render these updates obsolete.
 - There is always a risk of change in the future but it is a poor reason for leaving a document in a form that is already out of date when republishing it as an EN.
 - These risks should be reduced by using common databases for storing the information used to construct the message documentation (see 2.4.5 and note that tools used in this study and the HL7 Version 3 documentation are both supported by underlying MS Access databases).

Recommendation 10 CEN TC251 should instruct authors of future and revised message standards, to conform to the style guide referred to by Recommendation 9.

2.3 Information model content

2.3.1 Data types

The smallest units in which the content of the information models and messages are specified are referred to as Data Types. CEN TC251 messages have always been based on a few simple (or primitive) Data Types. These have been extended by compound Data Types built from combinations of the simple Data Types and more complex types referred to as Common Subclasses (Common Attribute Groups in the first message standards). As part of this study several detailed documents concerned with Data Typing were studied and reviewed. This material is summarised in Annex G ([MsgAlign-G-04-DataTypes.doc](#)).

Consideration of the current CEN TC251 Data Types in the light of this study led to the conclusion that there are several weaknesses in the current application of Data Types and Common Subclasses in CEN TC251 message standards.

- ❖ Inclusion in the list of Common Subclasses of a few domain specific "subclasses" such as "repeat medication information".
 - These should be modelled classes; or
 - Listed separately from the "Common Subclasses".
 - Note: No specific recommendation here as the report includes other proposals for representation of Common Subclasses (2.4.5)
- ❖ No clear distinction between different types of identifiers.
 - "Real World Identifiers" such as patient numbers.
 - "Technical Instance Identifiers", such as message and record component identifiers.
 - "Technical Instance Locators", such as URLs and phone numbers.

Recommendation 11 CEN TC251 WGI should consider the advantages and disadvantages of making distinction between the representation of Real Word Identifier, Technical Instance Identifiers and Technical Instance Locators.

- ❖ The description of "Real" numbers does not indicate the significance of decimal places provided.

Recommendation 12 CEN TC251 WGI should propose a modification to the description of the R [Real number] type to enable the precision of the value to be included where appropriate.

- ❖ Little attention has been given to formally specifying the Value Domains (lists or ranges of permissible values) for attributes.

Recommendation 13 CEN TC251 should instruct authors of future and revised message standards to analyse and, where possible document, the Value Domains for the attributes or all classes in the model. A form for documenting Value Domains should be discussed and agreed in CEN TC251 WGI.

2.3.2 Overlapping content

CEN TC251 message standards have overlapping content. These overlaps are of different types and have different levels of significance when considering alignment between messages.

- ❖ Duplication of definitions and content;
- ❖ Variation between similarly named classes;
- ❖ Different names applied to conceptually similar classes;
- ❖ Overlaps of scope and gaps between the scope of different messages or sets of messages (see 2.5).

Resolving overlaps requires a combination of three factors:

- ❖ Agreement on which issues need to be formally resolved;
- ❖ A mechanism for presentation of elements that are common to all (or many) message standards;
- ❖ Practical implementation of that mechanism.

2.3.3 Duplication of definitions and content

2.3.3.1 *Is duplication a problem?*

Duplication of content increases the bulk of each message standard. However, this is not the most significant problem. Indeed some people prefer duplication since it ensures that all the information required is available to the reader.

A more important issue is that duplication permits deliberate or inadvertent deviation between messaging standards. The authors of a message standard may of their own volition, or based on comments, modify the description or content of a class used in other message standards. The change may appear insignificant or positively advantageous but it is still a change. If such variations are possible, an implementer needs to read several versions of very similar material to ensure that there are no differences.

Changes to an apparently common component may indeed be beneficial. Such a change may remove an earlier ambiguity or enhance the ability of a class to meet requirements identified in use or earlier messages. In this case the change should also be applied to all message standards that share the common component. Identifying all occurrences of such common classes is at least time-consuming and at worst prone to errors of omission. Furthermore, the formal mechanisms of standardisation do not encourage the repeated resubmission of multiple documents for formal approval of the necessary changes.

2.3.3.2 *Removing duplication*

Once a common set of reusable classes and attributes are agreed these could be documented in one of two ways. These documented common components could then be referred to rather than individually documented in individual ENVs.

- ❖ Registration as provided by ENV 12537 (Registration of information objects used for EDI in healthcare)
- ❖ One or more foundation Standards could be drafted to cover common components that are agreed as a stable basis for further development.

Issues other than duplication of content affect the relative merits of these two approaches and a detailed discussion is included later in this report (see 2.3.4).

2.3.4 Variations in content and data structure

2.3.4.1 Analysis of variation in classes across nine message standards

Variations and overlaps in data structure have been analysed using a database, which has been made available with the electronic version of this report ([MsgAlign.mdb](#)). The results of this analysis are summarised in Table 3. An expanded account of this analysis is also available in Annex B ([MsgAlign-B-04-ClassesAnalysisTable.doc](#)).

Table 3. Summary of class name analysis

Documents analysed	9
Classes and subclasses and attributes with distinct names (including those formerly referred to as "attribute groups" and "common attributes groups")	378
Attributes with distinct names	> 1,100
Attributes and classes with distinct roles This figure is significantly <i>smaller</i> if the scope of a concept is broadened to the extent embodies in the EHCR Architecture and prENV13606-4.	< 1,000
Attributes and classes with same conceptual role or function but with a different name. This figure is significantly <i>larger</i> if the scope of a concept is broadened to the extent embodies in the EHCR Architecture and prENV13606-4.	> 100
Attributes that are distinct taking account of the containing class and the attribute name.	> 3,500
Classes and subclasses that are reused in more than one of the documents analysed (i.e. same name and same purpose)	86
Classes and subclasses that are reused in 4 or more of the documents analysed (i.e. same name and same purpose)	25

2.3.4.2 Variation between similarly named classes

Existing message standards contain examples in which a class defined in an earlier message is embellished with additional attributes or constraints in subsequent message standards. This poses the question of whether such a class should be renamed to make the distinction clear or whether it should be left unchanged so that the common purpose of this class clear. This is not an easy choice.

Generally if the concept represented is the same, the name is unchanged. The intention in these cases is usually that the enhanced version of the class should eventually be used in all messages. However, there are no formal mechanisms for:

- ❖ Checking with experts in the previously covered domain to ensure that this enhancement is appropriate.
- ❖ Capturing the changes and applying them to earlier standards.

2.3.4.3 Do these variations cause real problems?

There are two different views about variations in content and structure of classes that represent similar concepts.

- ❖ The purist view is that variations should be avoided unless the distinction between the two similar classes has been appropriately modelled.

In this view, any variations between different uses of the same class indicate shortcomings of initial analysis or inappropriate naming of classes.

Either the original user failed to fully analyse the modelled class or the second use the two classes represent different concepts and should therefore have different names.

- ❖ The alternative view is that variations in representation of the same concept in different contexts may be an appropriate reflection of business needs.

In this view, the same class can have different attributes in different messages as a consequence of the need for different information to be communicated.

This study suggests that both these views represent a part of the picture. There are some examples of changes to classes between ENV1613 and more recent ENVs that correct anomalies or incompleteness in the original classes. However, there are also examples of additions to or restrictions of flexibility in earlier classes that do not imply errors or omissions in earlier work.

The process of defining a usable message is not about describing every facet of everything referred to in the message. Instead the task is to unambiguously represent the facets about which the parties need to communicate while avoiding the inclusion of extraneous noise.

Example 1:

- ❖ All samples have colour, shape, state and texture so should all messages that include information about samples enable these facets to be communicated?

- A clinician submitting a biopsy specimen for histological examination may need to provide structured information about these facets, but ...
- A phlebotomist submitting a blood sample for routine biochemical tests will not wish to provide similar information.

We may consider the biopsy specimen and the blood sample to be specialisations of the general class "sample". This allows a complete and consistent view to be sustained. However, in an individual message these generalised structures will include attributes that are never used. There are two options:

- i Include all the detail but indicate that it is not required in the domain. This leads to greater complexity and makes validation more difficult.
- ii Document the specialisation as a refined class containing only the information required to meet a specified purpose.

The "blood sample" is a "sample" but that, in the context of a routine investigation, the properties of colour, shape, state and texture are not supported. If the message specification is equivocal and leaves the decision to the sender of the message, then the receiving system must be designed to deal with receipt of information it does not require.

Example 2:

- ❖ Should a patient always be regarded as a specialisation of a "subject of investigation"?
- In the laboratory context an animal or inanimate object may also be the subject of an investigation (i.e. swab from theatre table).
- On the other hand, an "inanimate object" is never a "subject of care" in the sense that a "patient" or "animal" may be.

Evidence of previous work suggests that some classes will vary between different messages for completely logical reasons. The usage of the same common class may also be subject to different implementation rules in different contexts. For example, a patient name and address may be essential in some administrative/registration messages but may be optional in clinical messages exchanged between parties with access to common register of patients. Therefore a mechanism is needed that allows the specification of additional context specific rules for some common classes.

Example:

The dates of some events may be defined to the second (e.g. for a timestamp) while varying degrees of optional imprecision may be permitted for other dates (e.g. for the date of a past operation as reported by a patient). This could be done by registering variants or by providing a mechanism for documenting such variants in individual message Standards.

This issue has already been addressed by a recommendation related to the differences in approach between CEN TC251 and HL7 Version 3. The recommendation is repeated here for ease of reference.

Recommendation 3 CEN TC251 should consider defining mechanisms for enabling (and where appropriate restricting) profiling of classes in ways that retain their connection to the underlying model while reducing complexity and redundancy in messages.

2.3.4.4 Different names applied to conceptually similar classes

There are also many cases where naming conventions applied to earlier message standards do not fit with the requirements of another domain. Thus "laboratory service order" in ENV1613 became "diagnostic service request" in ENV12539. Many attributes and related classes were renamed to align with this change even though the concept represented was unchanged and certainly the nature and role of most attributes were unchanged except in name.

It is not necessarily right or wrong to use more specific names, which suit particular uses of a more general class. It may also be useful to amend the descriptive text and examples and permitted values. However, the convention of fully specifying the names of attributes obscures the extent of the similarity between classes and prevents reuse of descriptive text. The combination of this with the lack of a formally specified and maintained Reference Information Model results in subsequent divergence in the representation and constraints applicable to similar concepts.

Two recommendations made earlier in this report relevant to this problem and are repeated here:

Recommendation 1 CEN TC251 should consider the options for rationalising and maintaining alignment of future message content by developing and maintaining or participating in the development and maintenance of a healthcare message Reference Information Model.

Recommendation 7 CEN TC251 should adopt formal conventions for class and attribute naming and for the typography of references to classes and attributes in the text of the standard. The nature of these rules is suggested in 2.2.5.

2.4 Management of overlapping content

2.4.1 Introduction

As identified earlier in the report there are two distinct ways of managing overlaps in content between different message standards.

- ❖ A register
- ❖ A Reference Information Model
- ❖ Foundation Standards covering stable common components.

The relative merits of these approaches are discussed below.

2.4.2 A Registration based approach

There are several possible bases for a registration-base approach

- ❖ ENV 12537 (Registration of information objects used for EDI in healthcare) has provided a framework for a register of data elements but as yet there is no formal registration authority.
- ❖ At the ISO level
 - The Basic Semantic Repository (BSR) is now being implemented.
 - ISO11179 sets out more flexible mechanism for registration of data elements.
- ❖ Within the World Wide Web community there are various proposals for or prototypes of XML based repositories.
- ❖ Various other resources also have parallels with or could provide initial input to registers. For example, the HL7 Version 3 RIM and the database used by the author to draft ENV13606-4 and to undertake analyses for this study.

The registration approach has the advantage that it is flexible and extensible. Since ENV12537 is already in force it needs no further Standardisation activity. It has the disadvantage that it requires an effective Registration Authority (something that has not been easy to establish in the past).

A registration-based approach faces two opposing risks.

- ❖ Too open an approach, allowing anything to be registered. This adds content without harmonisation and will do little to resolve the duplication problem.
- ❖ Too restrictive an approach, imposing constraint on registration. This may impede the definition of new or variant classes needed in future messages.

These two problems could be addressed if the register was controlled and managed by CEN TC251 through WGI. In this case, any additions required for new messages would be added at the request of the team responsible for developing the message and with the consent of the Working Group. This is less open than the procedures specified by ENV12537 but the motivation for maintaining the register would rest with those responsible for its control. Most of the material required to facilitate this approach is already in place. However, establishing such a registration process would have resource implications. An individual or organisation would need to take responsibility for the actual maintenance of the database on behalf of the Working Group.

A register entirely managed by CEN TC251 may appear rather insular in a world where there are shared problems and concepts, which are global rather than European and which extend beyond the domain of healthcare. However, ISO11179 envisages sector specific Registration Authorities and makes some pragmatic observations about the nature and control of the registration process (see Table 4). Therefore it is reasonable to envisage a registration effort by CEN TC251 WGI becoming part of the ISO procedure by subsequent recognition of the TC as a Registration Authority under this ISO11179.

Table 4. Excerpt from ISO11179 regarding Registration Authorities and procedures

Registration of Data Elements, ISO/IEC 11179-6, provides instruction on how a registration applicant may register a data element with a central Registration Authority and the allocation of unique identifiers for each data element. Maintenance of data elements already registered is also specified in this document.

The uniqueness of a registered data element is determined by the combination of the Registration Authority Identifier, the unique identifier assigned to a data element within a Registration Authority, and the version. They are also included in widely available Registries of data elements. Each registry is maintained by a Registration Authority to which data elements logically and functionally belong. For example, data elements related to chemical matter would likely be registered under a Chemical Manufacturer Registration Authority. The Registries should be indexed and constructed so that those designing applications or messages, such as EDI, can ascertain easily whether a suitable data element already exists. Where it is established that a new data element is essential, the procedure should encourage its derivation from an existing entry with appropriate modifications, thus avoiding unnecessary variations in the way similar data elements are constructed. Registration will also allow two or more data elements serving an identical function to be identified, and more importantly, it will identify situations where similar or identical names are in use for data elements that are significantly different in one or more respects.

Registration is more complex than a binary status simply indicating whether a data element is either registered or not. Although it is tempting to insist that only "good" data may be registered, that is not practical. Therefore, improvement in the quality of registered data is divided into three levels (called registration status): recorded data element, certified data element, and standardized data element. In addition, there are status levels for administration between each of these quality levels. Collectively, these status levels are called administrative status. They indicate the point in the registration life cycle currently attained by a registered data representation.

2.4.3 A Reference Information Model

A Reference Information Model (RIM) of the type maintained by HL7 Version 3 is a variant of the registration approach. However, the RIM concept is subservient to a particular development method. Therefore, the meta-model that underlies the RIM is also under the control of the organisation that maintains it.

This offers few advantages in respect of registration of common components that represent the individual building blocks of a message standard. However, the advantages of the RIM approach become apparent when the wider picture is considered. A RIM can be designed to support tools that validate relationships, maintain internal consistency and enable generation of documents. As additional requirements for recording model constraints or for generating alternative electronic or documentary forms become apparent these can be met more readily by a RIM approach.

The database used by the author of this report when creating ENV12539 and ENV13606-4 amounts to a rather informal and poorly documented RIM. It includes the basic registration information specified in ENV12537 (Registration of information objects used for EDI in healthcare) but has been substantially extended to support additional information required for modelling and generation of standards documents in the forms used by CEN TC251 WGI.

The EHCR Communication Standards (ENV13606) include specifications of general types of record component (component complexes and component items). These appear to provide a foundation for redefining many classes in current message standards in a more consistent way as part of a Reference Information Model. The relationship between the classes and subclasses in existing messages and general underlying EHCR concepts and more fundamental types is outlined in Annex H ([MsgAlign-H-04-EhcrAndRim.doc](#)).

2.4.4 A foundation Standard approach

A set of foundation Standards including the main elements common to most of the existing messages is inherently less flexible than a register. It requires a formal drafting comment and acceptance procedure. However, there are significant attractions in this approach.

- ❖ A stable baseline could be presented in the same documentary form as the message standards. This would ease referencing and enhance consistency without depending upon procedures for maintaining and publishing a register.
- ❖ The effort of producing such foundation Standards would be limited, since most of the material already exists in the current message standards.
- ❖ Message standard would be able to refer to the foundation Standard(s) as a Normative reference rather than referring to a potentially less stable or less accessible register.
- ❖ If the approach is limited to the genuine common classes about which consensus can be achieved, the limitation of flexibility may be an advantage rather than a disadvantage.

2.4.5 Conclusions

The approaches are not mutually exclusive. Foundation Standards could be used to represent data types and frequently used common components. A Register could be used to record more specific classes that may also be used in several message standards. A Register maintained within CEN TC251 could form the backbone for a more flexible RIM used to generate and maintain message standards.

This hybrid approach appears to offer many advantages. It would allow the basic building blocks to be specified in an accessible and stable form (as published Standards) while allowing refinement and development of specific classes and messages. If this general thesis is accepted, the four areas identified in Table 5 appear ready for conversion to foundation standards.

Table 5. Potential candidate areas for drafting of foundation standards

Data types and common subclasses	This would be based on the overlapping common subclass content of the ENV13606-4, ENV13607 and ENV13609-2. Possible minor revisions and additions informed by discussions in CEN TC251 WGI, ISO TC215 WG2 and the documentation produced by HL7 in relation to data types.
Healthcare agents	This would be based on the current models of healthcare agent used in ENV13606-4, ENV13607 and ENV13609-2. Possible minor revisions and additions informed by experience of implementation and suggestions for further simplification. (See Annex C MsgAlign-C-04-HcAgents.doc)
General message components	This would be based on the common elements regarding communicating parties, message identification, issue dates, references between messages and other components used at the top level of most or all healthcare messages. Again this would be based on the content of ENV13606-4, ENV13607 and ENV13609-2 with revisions and additions informed by implementation experience.
Patient matching / administrative data	This could be based on the Patient Matching Information in ENV13606 and the Patient details class from ENV12612.

Recommendation 14 CEN TC251 WGI should submit formal work item proposals to CEN TC251 for the rapid development of a four part European Standard covering the following common aspects of healthcare messaging:

- Data types and common subclasses*
- Healthcare agents*
- General message components*
- Patient matching / administrative data*

In addition to the development of these foundation standards the practical consequences of following the suggested mapping of classes and attributes EHCR concepts and more fundamental types as outlined in Annex H ([MsgAlign-H-04-EhcrAndRim.doc](#)).

The following recommendation made earlier in this report is repeated here:

Recommendation 1 CEN TC251 should consider the options for rationalising and maintaining alignment of future message content by developing and maintaining or participating in the development and maintenance of a healthcare message Reference Information Model.

Recommendation 15 CEN TC251 consider taking responsibility as a Registration Authority under the terms of ISO11179 and/or sharing such a responsibility with HL7 to encourage consistent specification of data elements for use in healthcare messages. A key issue will be to harmonise the requirements of ISO11179 with the need for a Reference Information Model.

2.5 Domain boundaries and general messages

2.5.1 *The issue*

The decision on the breadth of a messaging domain is always arbitrary. Usually it is based on a pragmatic balance that aims to avoid the problems produced by either extremely narrow or very broad domains.

- ❖ Narrow domains lead to duplication of material that deals with large areas of commonality.
 - For example, all CEN TC251 ENVs repeat the information designed for matching a specific patient to the content of the message.
- ❖ Narrow domains may lead to failure to recognise common ground with other domains and this may lead to various solutions to the same problem.
 - For example, ENV1613 failed to recognise the requirement to identify messages irrespective of the message domain. Thus it was left to the next generation of messages to state that each message sent by an originator should have an identifier assigned by the sender that is unique across all healthcare messages. This allows any message to refer to another message where this is relevant.
- ❖ Narrow domains may mean that some general issues are not perceived to be in a specific scope and thus these are left unresolved.
 - For example, there is a case for a general messages for acknowledgement and this has been recognised by most project teams but not addressed within any specific domain because of its general impact.
- ❖ Broad domains lead to higher levels of abstraction and flexibility. These may make implementation of a message for a specific purpose unduly complex. More particularly they lead to a requirement for a large volume of implementation guidelines which inevitably focus on narrower domain.
 - For example, most pathology reports are inherently simple but because ENV1613 covers a broad domain the simplicity is obscured by mechanisms designed to make microbiology reporting possible. In practice, this complexity has rarely (if ever) been used because the level of structuring supported by actual microbiology systems is less than or does not match the message structure. Separate standards addressing particular pathology domains might have resulted in several simpler report messages specific to particular sub-domains or sub-types of results.

2.5.2 Possible ways forward

Adoption of common classes either in a specific EN or in register will shrink those parts of individual message Standards concerned with common elements and common requirements. This should reduce the extent of duplication and the risk of unnecessary divergence associated with narrow domains. The work involved in preparing separate Standards covering different aspects is also reduced. This therefore tips the balance in favour of narrower domains than those worked on so far in CEN TC251.

Introduction of separate Standards or parts of Standards concerned with a particular sub-domain should allow clearer exposition of the aspects that are specific to a particular message.

- ❖ For instance, splitting ENV1613 into “Microbiology” and “Other” pathology reports would enable both topics to be covered more simply. The special provisions for microbiology would be set out only in the context where needed. Use of common elements would avoid unnecessary divergence.

How far such subdivision should go is an open question. There is little point in subdividing simply because a different discipline is involved. Furthermore, we need to be aware of another risk from having many subtly different messages. The application (or perhaps even the user) will need to select a message for a particular communication. Therefore, there is no merit in subdivision except where it produces obvious simplification.

Subdividing a domain into three or four parts presents a danger of a proportionate multiplication of the number of messages. Taking the pathology domain as an example, simple subdivision would multiply the number of request, modification and cancellation messages as well as the number of report messages. This seems wasteful, as there are few differences between request messages in current domains (including pathology, radiology and referral). In the case of cancellation messages, these are practically identical across all domains and message types. It would therefore be wise to consider some common message types that can be specified once and used in various different domains.

At the same time some general issues missed in previous work could be dealt with. For instance the specification and use of cancellation and acknowledgement messages are general rather than specific to a particular domain.

Table 6 proposes a way forward. The intentions of this proposed approach are:

- ❖ To draw together common strands;
- ❖ To reduce duplication of effort;
- ❖ To separate those aspects of particular domains that are specialised;
- ❖ To produce a readily accessible set of messaging standards that meet the combined scope of all messages so far developed.

Recommendation 16 CEN TC251 should amend its Work Programme in respect of the revision of the current messaging Prestandards. Replacement Work Items should be considered involving drafting seven multipart Standards covering the scope areas outlined in Table 6. The content of these Standards should be based on existing material in the Prestandards wherever possible with modification based on experiences with implementation. The style of presentation shall be as specified in the style guide proposed by Recommendation 9 .

Table 6. Proposed reorganisation of the CEN TC251 messaging domain

Possible topic groups and sub-topics	Existing relevant work
a) General purpose message components (See Table 5)	
i Data types and common subclasses	All
ii Healthcare agents	ENV13606 + ENV1307
iii General message components (e.g. "headers")	All
iv Patient matching / administrative data	
b) General purpose messages	
i Acknowledgement message(s)	Not covered but relevant to all
ii Cancellation message(s)	All
iii General provisions applicable to modifications messages.	All
c) Service requests and reports	
i General messages for requesting and reporting (see also separate specialised requests and reports sections below). Primarily concerned with the message content to support general aspects such as sequences, references between messages. The actual "payload" of the message such as specifics about the requested service and results should be left unfilled.	ENV1613, ENV12538, ENV12359, PT32 part
ii Requests for investigations on samples (with requests to take a sample)	ENV1613 +/- ENV12539
iii Requests for investigations/diagnostic services on patients	ENV12539 +/- ENV12538
iv Pathology reports general	ENV1613
v Microbiology reports	ENV1613
vi Diagnostic service reports based on samples (e.g. anatomic pathology)	ENV12539 +/- ENV1613
vii Diagnostic service reports based on procedures applied to a whole patient (e.g. radiology).	ENV12539
viii Reports involving multiple patients, transfusions, donors, neonatal, etc.	PT32 part +/- ENV12539
d) Treatment requests and delivery	
i Prescribing and dispensing for individual patients	ENV13607
ii Blood transfusion - patient centric exchanges	PT32 part
e) EHCR information communication	
i Requests for EHCR information.	ENV13606-4
ii EHCR information in service requests (i.e. in a referral)	ENV12538 + ENV12539 + ENV13606-4
iii EHCR information in service report (e.g. outpatient or discharge report)	ENV12538 + ENV13606-4
iv Provision of EHCR information to support transfer	ENV13606-4
v Exchanges of EHCR information in to support shared care	ENV13606-4
f) Administration	
i Individual patient information	ENV12612
ii Patient list transactions	ENV12612
g) Supporting information and common classes	
i Communication of coding scheme information used in other messages	EN13609-1
ii Communication of other supporting information	ENV13609-2
iii Communication of directories of information referred to in other messages (e.g. Healthcare Parties, Distribution Rules)	?

2.6 Overlap with other Prestandards

The main focus of this study was on the overlaps and variations in presentation of different messaging standards. However, messaging is only one way of communicating and since the message specifications are designed to be syntax independent it seem desirable for alignment to extend beyond the context of traditional messaging.

As noted earlier in the report the method, content and style of presentation have all followed an evolutionary path. Therefore separation between Working Groups, has made divergent styles, and differences in resolution of common questions a "Darwinian" inevitability. This misalignment is evident in several documents but is most obvious when comparing any of the messaging standards with ENV12018 (Identification, administrative, and common clinical data structure for Intermittently Connected Devices used in healthcare – including machine-readable cards). There are some data elements in ENV12018 that are specific to the use of card technologies or at least to technologies where capacities and band-width are limited. However, the style of presentation, naming conventions and actual content of many conceptually similar elements differ.

As noted earlier this is an inevitable effect of the separation between the Working Groups responsible for the two areas of work. On the one hand, ENV12018 may be more technically precise; on the other hand, perhaps it is less readable to the casual observer. The real issue for applications that wish to communicate using messages and cards is that the content, structure and presentation should be more recognisably aligned. Since formal technical responsibility for revision of ENV12018 resides within WGI it should be possible to achieve this end.

Recommendation 17 CEN TC251 should advise the authors of the revised of ENV12018 that they should seek to deliver the revised version of the Standard in a form that:

- Is aligned with the presentation of message standards as recommended in this report.*
- Makes use of common components and data types defined in message standards.*
- Wherever possible, taking account of the technical issues particular to cards and other intermittently connected devices, represent concepts in a manner similar or identical to that applied to the equivalent concept in message standards.*

Recommendation 18 CEN TC251 WGI should consider any problems reported by the authors of ENV12018 while trying to undertake revisions in line with Recommendation 17 . The WG should determine whether these are specific to the technical scope of ENV12018 or are more general issues that require revision to the methods and form of presentation or resolution of information modelling differences.

2.7 International perspectives

2.7.1 Introduction

Table 7 lists the Annexes to this report that are specifically relevant to comparison of CEN TC251 message standards with similar work outside Europe.

Table 7 Annexes relevant to the International component of this study

Annex E	An inventory of existing non-European initiatives in healthcare messaging with cross-reference to relevant CEN TC251 message standards.
Annex F	A summary of the HL7 Version 3 Message Development Framework indicating similarity and variation between this and the CEN TC251 method.
Annex G	A comparison of Data Types supported by CEN TC251 with those supported by HL7 and the recommendations and definitions of ISO11179.
Annex H	An analysis that categorises the classes identified in Annex and considers how they relate to the more general record component classes specified in the EHCR Communication Prestandards (ENV13606)

2.7.2 ISO TC215 WG2

The first meeting of ISO TC215 WG2 (Messages and Communications) in January 1999 recommended that priority should be given to work that would standardise a single method for healthcare message development. This method would be based on, and would form a synthesis of message development methods used by CEN TC251 and HL7.

There are some immediate positive statements that can be made in this respect:

- ❖ The HL7 Version 3 Message Development Framework (MDF) is based closely on the CEN TC251 approach to message development documented in CR12587.
- ❖ HL7 MDF and the current CEN TC251 work uses a similar subset of UML to model its messages. There are several significant differences in the end product. The most obvious differences are:
 - The HL7 overarching Reference Information Model (RIM);
 - Differences in documentation style;
 - Differences between CEN TC251 scenario descriptions and the HL7 approach to "trigger" events and "responsibilities" of the receiving system;
 - Differences in data content;
 - Differences in modelling of clinical information.
- ❖ The first meeting of ISO TC215 WG2 recommended to the ISO TC a Standard for a common message development method based on the HL7 MDF revised as necessary to take account of CEN needs and experience.
- ❖ The availability of MS Access files containing the HL7 Version 3 RIM and associated tools for manipulation of this information will facilitate comparison of:
 - The methods, database structure and tools used for message modelling;
 - The content and structure of the models and resulting messages.

At the April meeting of ISO TC215 WG2 this proposed work item was endorsed and the agreed first step was to review the HL7 Version 3 MDF to determine what part of this could be adapted to create an ISO message development method.

Progress was made on this commitment but at the July meeting it was clear that some experts involved in both the CEN and ISO processes were unconvinced of the value of this process. Several experts suggested that a common method without a common Reference

Information Model might not be useful. Thus it was agreed that consideration should be given to the potential for alignment of the models used by CEN with the HL7 RIM.

The debate in ISO TC215 WG2 emphasised the need for a coherent future path rather than proposing the adoption of extant messages from any existing standards development group. However, the relevance of standards is measured in the extent to which they are useful, used and safe.

2.7.3 Potential for alignment with HL7

As agreed by the TC the strategic focus of the International element of this report was on alignment with HL7 and in particular the relationship with Version 3. It will be evident to readers of this report that several of the activities and changes recommended in this report are based on ideas gleaned from study of the HL7 method and RIM.

These are early days in the development of International Standards in health informatics and the manner in which future development will take place is unclear. However, what has emerged already is that the active members of the messaging task force in ISO TC215 WG2 are almost exclusively active participants either in CEN TC251 or in HL7. The most of those from HL7 are particularly active in the development of Version 3. The strategic starting point of the international element of this study was to investigate the potential for alignment and co-operation between CEN TC251 and HL7. The initial evidence from ISO meetings and from informal discussions with HL7 members is that this desire is reciprocated.

There remains uncertainty about the form that this co-operation will take. This arises from the need to focus time and resources on local and immediate objective and concerns about the additional burden of ISO activities on already busy experts. Members of HL7 have expressed the view that formal standards bodies such as CEN and ISO may be less responsive than the "purpose designed" structures of HL7. Thus, there is willingness to work together and recognition of the benefits of sharing our experience and creating common stable global standards but uncertainty about the best way of achieving this.

2.7.4 Study recommendation in the context of International co-operation

This report has recommended many changes to the approach taken to message development within CEN TC251. However, effecting these changes will require the time and commitment of experts who are seeking to balance the demands of working within the ISO environment with continued support for the efforts of CEN. Therefore, it is reasonable to ask whether it is feasible to carry through the proposed recommendations. Would it perhaps be better to focus all our efforts in the ISO arena? The difficulty here is that the messaging group in ISO WG2 consists of those from HL7 and CEN. If we cease to develop messages in CEN, then perhaps the CEN experts' time would be better spent in HL7 rather than in an additional ISO grouping peripheral to the actual development process.

Thus CEN TC251 faces a difficult choice

- ❖ to update its approach to message development in a way that will not only improve the harmonisation of CEN messages but will also assist in alignment with activities outside Europe.

or

- ❖ to find alternative ways to ensure the European requirements for healthcare messaging are well-supported by the development in other messaging standard groups such as HL7.

An urgent debate to find an answer to this question is the subject of the final recommendation of this report.

Recommendation 19 CEN TC251 should decide how best to meet the requirements of healthcare providers and system providers in respect of healthcare messaging and communication. This decision should take due account of:

- the extensive proposals for enhancing and realigning CEN healthcare message standards contained in this report.*
- the need for substantial resource commitments from CEN or from expert volunteers to successfully complete these activities.*
- changing national, regional and global situations in relation to requirements for healthcare communication*
- the role of other organisations involved in healthcare message standardisation (such as HL7, ISO and EBES) and European, national, service provider and industrial views of these organisations and their deliverables.*

3 Summary of recommendations

Recommendation 1 CEN TC251 should consider the options for rationalising and maintaining alignment of future message content by developing and maintaining or participating in the development and maintenance of a healthcare message Reference Information Model.

Recommendation 2 CEN TC251 should extend the deliverables of CEN message standards to include a specification of the interactions that result in the exchange of particular message types. Following a similar approach to the HL7 Version 3 Interaction Model each interaction should be specified in relation to the roles and responsibilities of sending and receiving applications and the message exchanged between them.

Recommendation 3 CEN TC251 should consider defining mechanisms for enabling (and where appropriate restricting) profiling of classes in ways that retain their connection to the underlying model while reducing complexity and redundancy in messages.

Recommendation 4 CEN TC251 should instruct authors of future and revised message standards that all model diagrams should be presented using the subset of UML, diagrammatic style and tabular representations of the class descriptions used in ENV13606-4, ENV13607 and ENV13609-2.

Recommendation 5 CEN TC251 should instruct authors of future and revised message standards to adopt a common document structure and to follow common conventions for naming sections and figures within the document.

Recommendation 6 CEN TC251 should instruct the authors of all future and revised message standards to exclude network presentations of GMDs from the published standards. This does not preclude this and other developmental material being made available in electronic forms as additional supporting material.

Recommendation 7 CEN TC251 should adopt formal conventions for class and attribute naming and for the typography of references to classes and attributes in the text of the standard. The nature of these rules is suggested in 2.2.5.

*Recommendation 8 CEN TC251 should instruct authors of future and revised message standards to follow ISO directives but should advise them **not** to use the ISO templates for this purpose.*

Recommendation 9 CEN TC251 should instruct WGI to develop and adopt a style guide for future message standards. This should be accompanied by an example document including a single example of each of the styles, figures and table formats specified. The starting point for this should be the draft provided as Annex D to this report.

Recommendation 10 CEN TC251 should instruct authors of future and revised message standards, to conform to the style guide referred to by Recommendation 9.

Recommendation 11 CEN TC251 WGI should consider the advantages and disadvantages of making distinction between the representation of Real Word Identifier, Technical Instance Identifiers and Technical Instance Locators.

Recommendation 12 CEN TC251 WGI should propose a modification to the description of the R [Real number] type to enable the precision of the value to be included where appropriate.

Recommendation 13 CEN TC251 should instruct authors of future and revised message standards to analyse and, where possible document, the Value Domains for the attributes or all classes in the model. A form for documenting Value Domains should be discussed and agreed in CEN TC251 WGI.

Recommendation 14 CEN TC251 WGI should submit formal work item proposals to CEN TC251 for the rapid development of a four part European Standard covering the following common aspects of healthcare messaging:

- Data types and common subclasses*
- Healthcare agents*
- General message components*
- Patient matching / administrative data*

Recommendation 15 CEN TC251 consider taking responsibility as a Registration Authority under the terms of ISO11179 and/or sharing such a responsibility with HL7 to encourage consistent specification of data elements for use in healthcare messages. A key issue will be to harmonise the requirements of ISO11179 with the need for a Reference Information Model.

Recommendation 16 CEN TC251 should amend its Work Programme in respect of the revision of the current messaging Prestandards. Replacement Work Items should be considered involving drafting seven multipart Standards covering the scope areas outlined in Table 6. The content of these Standards should be based on existing material in the Prestandards wherever possible with modification based on experiences with implementation. The style of presentation shall be as specified in the style guide proposed by Recommendation 9 .

Recommendation 17 CEN TC251 should advise the authors of the revised of ENV12018 that they should seek to deliver the revised version of the Standard in a form that:

- Is aligned with the presentation of message standards as recommended in this report.*
- Makes use of common components and data types defined in message standards.*
- Wherever possible, taking account of the technical issues particular to cards and other intermittently connected devices, represent concepts in a manner similar or identical to that applied to the equivalent concept in message standards.*

Recommendation 18 CEN TC251 WGI should consider any problems reported by the authors of ENV12018 while trying to undertake revisions in line with Recommendation 17 . The WG should determine whether these are specific to the technical scope of ENV12018 or are more general issues that require revision to the methods and form of presentation or resolution of information modelling differences.

Recommendation 19 CEN TC251 should decide how best to meet the requirements of healthcare providers and system providers in respect of healthcare messaging and communication. This decision should take due account of:

- the extensive proposals for enhancing and realigning CEN healthcare message standards contained in this report.*
- the need for substantial resource commitments from CEN or from expert volunteers to successfully complete these activities.*
- changing national, regional and global situations in relation to requirements for healthcare communication*
- the role of other organisations involved in healthcare message standardisation (such as HL7, ISO and EBES) and European, national, service provider and industrial views of these organisations and their deliverables.*