# Smart Open Services for European Patients

Open eHealth initiative for a European large scale pilot of

Patient Summary and Electronic Prescription

# epSOS Architecture and Design

## EED DESIGN - Specification

## epSOS Common Modules

## CDA R2 Implementation Guide

| | |
|---|---|
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| Contributor | |

# Change history

| Version | Date | Status Changes | From | Review |
|---|---|---|---|---|
| V0.1 | 29/12/2012 | Initial Draft for Internal Review | Lombardy | KT 1.4.10 Implementation Team |
| V0.2 | 26/02/2013 | Final Draft for QA revision | Lombardy | KT 1.4.10 Implementation Team |
| V0.3 | 11/03/2013 | Included QA revisions | Lombardy | TPM; WP 3.A ; WP 3.B WP 3.C; KT 1.4.10 Implementation Team |
| V0.4 | 09/07/2013 | Included 3.9.1 errata and known issues | Lombardy | KT 1.4.10 Implementation Team |

# Table of contents

# 1 Introduction

This document defines the implementation's rules to be satisfied for claiming the conformance with the common CDA modules (header, sections, entries) used for the implementation of the epSOS Semantic Signifiers.

This version of this specification provides only few explicit implementation rules, all the other rules to be applied are provided by reference to the D 3.9.1 Appendix B1 [D3.9.1 B1].

This version includes also errata to be applied to the D 3.9.1 Appendix B1 [D3.9.1 B1] and a list of known issues to be discussed.

Future versions of this specification will progressively include the rules defined in the [D3.9.1 B1] making them explicit by means of the new formalism adopted.

## 1.1 epSOS Service to be Bound

- Patient Summary
- ePrescription
- eDispensation
- Medication Related Overview
- HealthCare Encounter Report

## 1.2 The Standard used for Binding

HL7 CDA Release 2 [CDAR2]

## 1.3 Related EED Design Documents

No

## 1.4 Conventions

This section describes the conventions used in this specification.

The conventions used are derived from the US Realm Consolidated[1] CDA specifications [CCDA].

### 1.4.1 Keywords

The keywords **SHALL, SHOULD, MAY, NEED NOT, SHOULD NOT,** and **SHALL NOT** in this document are to be interpreted as follows

**SHALL**: an absolute requirement

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**SHALL NOT**: an absolute prohibition against inclusion

**SHOULD/SHOULD NOT**: best practice or recommendation. There may be valid reasons to ignore an item, but the full implications must be understood and carefully weighed before choosing a different course

**MAY/NEED NOT**: truly optional; can be included or omitted as the author decides with no implications

| |
|---|
| The keyword "**SHALL**" allows the use of nullFlavor unless the requirement is on an attribute or the use of nullFlavor is explicitly precluded. |

The subject of a conformance verb (keyword) in a top-level constraint is the template itself. In nested constraints, the subject is the element in the containing constraint. Top-level constraints are those that begin with a number and are not indented.

### 1.4.2 Cardinality

The cardinality indicator (0..1, 1..1, 1..*, etc.) specifies the allowable occurrences within a document instance. The cardinality indicators are interpreted with the following format “m…n” where m represents the least and n the most:

0..1 zero or one
1..1 exactly one
1..* at least one
0..* zero or more
1..n at least one and not more than n

When a constraint has subordinate clauses, the scope of the cardinality of the parent constraint must be clear. In the next figure, the constraint says exactly one participant is to be present. The subordinate constraint specifies some additional characteristics of that participant.

**Figure 1: Constraints format – only one allowed**

1. **SHALL** contain exactly one [1..1] **participant**
   a. This participant **SHALL** contain exactly one [1..1] **@typeCode**="LOC" (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType)

In the next figure, the constraint says only one participant “like this” is to be present. Other participant elements are not precluded by this constraint.

**Figure 2: Constraints format – only one like this allowed**

1. **SHALL** contain exactly one [1..1] **participant** such that it
   a. **SHALL** contain exactly one [1..1] **@typeCode**="LOC" (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType)

### 1.4.3 Vocabulary Conformance

The templates in this document use terms from several code systems. These vocabularies are defined in various supporting specifications and may be maintained by other bodies, as is the case for the LOINC® and SNOMED CT® vocabularies.

Note that value-set identifiers (e.g., ValueSet `2.16.840.1.113883.1.11.78 Observation Interpretation (HL7)` **DYNAMIC** do not appear in CDA submissions; these identifiers tie the conformance requirements of an implementation guide to the appropriate code system for validation.

Value-set bindings adhere to HL7 Vocabulary Working Group best practices, and include both a conformance verb (**SHALL**, **SHOULD**, **MAY**, etc.) and an indication of **DYNAMIC** vs. **STATIC** binding. Value-set constraints can be **STATIC**, meaning that they are bound to a specified version of a value set, or **DYNAMIC**, meaning that they are bound to the most current version of the value set. A simplified constraint, used when the binding is to a single code, includes the meaning of the code, as follows.

**Figure 3: Binding to a single code**

**1. … code/@code**="11450-4" Problem List (CodeSystem: 2.16.840.1.113883.6.1 LOINC).

The notation conveys the actual code (`11450-4`), the code's displayName (Problem List), the OID of the codeSystem from which the code is drawn (2.16.840.1.113883.6.1), and the codeSystemName (LOINC).

HL7 Data Types Release 1 requires the codeSystem attribute unless the underlying data type is "Coded Simple" or "CS", in which case it is prohibited.

The `displayName` and the `codeSystemName` attributes are

1. Mandatory, for the coded elements that are subject of the epSOS transformation process
2. recommended, for all the other coded elements

The above example would be properly expressed as follows.

**Figure 4: XML expression of a single-code binding**

```
<code code="11450-4" codeSystem="2.16.840.1.113883.6.1"/>

<!-- or -->

<code code="11450-4" codeSystem="2.16.840.1.113883.6.1"
      displayName="Problem List"
      codeSystemName="LOINC"/>
```

A full discussion of the representation of vocabulary is outside the scope of this document; for more information, see the HL7 V3 Normative Edition 2010[2] sections on Abstract Data Types and XML Data Types R1.

[2] HL7 Version 3 Interoperability Standards, Normative Edition 2010. http://www.hl7.org/memonly/downloads/v3edition.cfm - V32010

There is a discrepancy in the implementation of translation code versus the original code between HL7 Data Types R1 and the convention agreed upon for this specification. The R1 data type requires the original code in the root. This implementation guide specifies the standard code in the root, whether it is original or a translation. This discrepancy is resolved in HL7 Data Types R2.

**Figure 5: Translation code example**

```
<code code='206525008'
      displayName='neonatal necrotizing enterocolitis'
      codeSystem='2.16.840.1.113883.6.96'
      codeSystemName='SNOMED CT'>
   <translation code='NEC-1'
      displayName='necrotizing enterocolitis'
      codeSystem='2.16.840.1.113883.19'/>
</code>
```

### 1.4.4 Containment Relationships

Containment constraints between a section and its entry are indirect in this guide, meaning that where a section asserts containment of an entry, that entry can either be a direct child or a further descendent of that section.

For example, in the following constraint:

1. **SHALL** contain at least one [1..*] **entry** (CONF:8647) such that it
    a. **SHALL** contain exactly one [1..1] **Advance Directive Observation** (`templateId:2.16.840.1.113883.10.20.22.4.48`)

the Advance Directive Observation can be a direct child of the section (i.e., `section/entry/AdvanceDirectiveObservation`) or a further descendent of that section (i.e., `section/entry/…/AdvanceDirectiveObservation`). Either of these are conformant.

All other containment relationships are direct, for example:

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.21"

The `templateId` must be a direct child of the section (i.e., section/templateId).

### 1.4.5 Null Flavor

Information technology solutions store and manage data, but sometimes data are not available: an item may be unknown, not relevant, or not computable or measureable. In HL7, a *flavor* of null, or `nullFlavor`, describes the reason for missing data.

Any **SHALL** conformance statement may use `nullFlavor`, unless the attribute is required or the `nullFlavor` is explicitly disallowed. **SHOULD** and **MAY** conformance statement may also use `nullFlavor`.

**Figure 6: Attribute required**

1. **SHALL** contain exactly one [1..1] **code/@code**="11450-4" Problem List (CodeSystem: LOINC 2.16.840.1.113883.6.1)
   or
2. **SHALL** contain exactly one [1..1] **effectiveTime/@value**

**Figure 7: Allowed nullFlavors when element is required (with xml examples)**

1. **SHALL** contain at least one [1..*] id
2. **SHALL** contain exactly one [1..1] code
3. **SHALL** contain exactly one [1..1] effectiveTime

```
<entry>
  <observation classCode="OBS" moodCode="EVN">
    <id nullFlavor="NI"/>
    <code nullFlavor="OTH">
      <originalText>New Grading system</originalText>
    </code>
    <statusCode code="completed"/>
    <effectiveTime nullFlavor="UNK"/>
    <value xsi:type="CD" nullFlavor="NAV">
      <originalText>Spiculated mass grade 5</originalText>
    </value>
  </observation>
</entry>
```

**Figure 8: nullFlavor explicitly disallowed**

1. **SHALL** contain exactly one [1..1] **effectiveTime**.
   a. **SHALL NOT** contain [0..0] nullFlavor).

## 1.5 Terms and Definitions

| | |
|---|---|
| PS | Patient Summary |
| eP | ePrescription |
| eD | eDispensation |
| MRO | Medication Related Overview |
| HCER | HealthCare Encounter Report |

## 1.6 Status of this Binding

The binding as defined in this document is a normative binding. All epSOS participating nations piloting the above mentioned epSOS services MUST conform this specification.

# 2 The Binding (normative)

## 2.1 Common Clinical Document Datatypes

This section is conceived for providing the rules for the epSOS Clinical Document datatype flavor, that is a set of reusable constraints that can be used within several elements defined in this guide, like:

- epSOS Address
- epSOS Telecom
- epSOS Patient Name
- epSOS Person Name
- etcetera,....

This version of this guide does not provide explicit rules for document datatypes.

Please refer to the D 3.9.1 Appendix B1 [D3.9.1 B1] for their definition.

## 2.2 Header

This section describes constraints that apply to the header for all the documents within the scope of the epSOS project.

Header's constraints specific to each document type are described in the appropriate specific EED Binding document (e.g. HCER bindings).

For this version of this guide only a subset of common header implementation rules are explicitly defined.

For those elements not hereafter mentioned please refer to the D 3.9.1 Appendix B1 [D3.9.1 B1] for their definition.

1. **SHALL** contain exactly one [1..1] **realmCode**.
2. **SHALL** contain exactly one [1..1] **typeId**.
    a. This typeId **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.1.3".
    b. This typeId **SHALL** contain exactly one [1..1] **@extension**="POCD_HD000040".
3. **SHALL** contain at least one [1..*] **templateId**
4. **SHALL** contain exactly one [1..1] **id**
    a. This id **SHALL** be a globally unique identifier for the document
5. **SHALL** contain exactly one [1..1] **code**.
    a. This code **SHALL** specify the particular kind of document (e.g. Patient Summary, HECR, eP, eD, MRO)
6. **SHALL** contain exactly one [1..1] **title**.

   a. Can either be a locally defined name or the display name corresponding to clinicalDocument/code.
7. **SHALL** contain exactly one [1..1] **effectiveTime**.
8. **SHALL** contain exactly one [1..1] **confidentialityCode**, which **SHALL** be selected from ValueSet epSOSConfidentiality 1.3.6.1.4.1.12559.11.10.1.3.1.42.31 **DYNAMIC**.
9. **SHALL** contain exactly one [1..1] **languageCode**, which **SHALL** be in the form nn-CC, such that
   a. The nn portion SHALL be selected from ValueSet epSOSLanguage 1.3.6.1.4.1.12559.11.10.1.3.1.42.6 **DYNAMIC**
   b. The CC portion, if present, SHALL be selected from ValueSet epSOSCountry 1.3.6.1.4.1.12559.11.10.1.3.1.42.4 **DYNAMIC**
10. **MAY** contain zero or one [0..1] **setId**.
   a. If setId is present versionNumber **SHALL** be present.
11. **MAY** contain zero or one [0..1] **versionNumber**
   a. If versionNumber is present setId **SHALL** be present

## 2.3 Section

This paragraph describes constraints that apply to the sections' templates used in the epSOS project, including:

1 Allergies and Other Adverse Reactions Section 1.3.6.1.4.1.19376.1.5.3.1.3.13
2 Immunizations Section 1.3.6.1.4.1.19376.1.5.3.1.3.23
3 History of Past Illness Section 1.3.6.1.4.1.19376.1.5.3.1.3.8
4 Coded List of Surgeries Section 1.3.6.1.4.1.19376.1.5.3.1.3.12
5 Active Problems Section 1.3.6.1.4.1.19376.1.5.3.1.3.6
6 History of Present Illness Section 1.3.6.1.4.1.19376.1.5.3.1.3.4
7 Medical Devices Coded Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.4
8 Procedures and Interventions Section 1.3.6.1.4.1.19376.1.5.3.1.1.13.2.11
9 Health Maintenance Care Plan Section 1.3.6.1.4.1.19376.1.5.3.1.1.9.50
10 Functional Status Section 1.3.6.1.4.1.19376.1.5.3.1.3.17
11 Coded Social History Section 1.3.6.1.4.1.19376.1.5.3.1.3.16.1
12 Pregnancy History Section 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4
13 Coded Vital Signs Section 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2
14 Coded Results Section 1.3.6.1.4.1.19376.1.5.3.1.3.28
15 .....

This version of this guide does not provide explicit rules for the section templates .

Please refer to the D 3.9.1 Appendix B1 [D3.9.1 B1] for their definition.

## 2.4 Entry

This paragraph describes constraints that apply to the entries used within the section utilized in the epSOS project, including:

1 Allergy and Intolerance Concern Entry Content Module 1.3.6.1.4.1.19376.1.5.3.1.4.5.3
2 Allergy and Intolerance Entry Content Module 1.3.6.1.4.1.19376.1.5.3.1.4.6
3 Immunization Entry 1.3.6.1.4.1.19376.1.5.3.1.4.12
4 Product Entry 1.3.6.1.4.1.19376.1.5.3.1.4.7.2
5 Problem Concern Entry 1.3.6.1.4.1.19376.1.5.3.1.4.5.2
6 Procedure Entry 1.3.6.1.4.1.19376.1.5.3.1.4.19
7 Problem Concern Entry 1.3.6.1.4.1.19376.1.5.3.1.4.5.2
8 Concern Entry 1.3.6.1.4.1.19376.1.5.3.1.4.5.1
9 Problem Entry 1.3.6.1.4.1.19376.1.5.3.1.4.5
10 Medical Devices Entry Content Module 1.3.6.1.4.1.12559.11.10.1.3.1.3.5
11 Pregnancy Observation Entry Content Module 1.3.6.1.4.19376.1.5.3.1.4.13.5
12 Vital Signs Organizer 1.3.6.1.4.1.19376.1.5.3.1.4.13.1
13 Vital Signs Observation 1.3.6.1.4.1.19376.1.5.3.1.4.13.2
14 Simple Observation Entry 1.3.6.1.4.1.19376.1.5.3.1.4.13
15 Social History Observation Entry Content Module 1.3.6.1.4.1.19376.1.5.3.1.4.13.4
16 Etcetera...

This version of this guide does not provide explicit rules for the entry templates .

Please refer to the D 3.9.1 Appendix B1 [D3.9.1 B1] for their definition.

# 3 Errata / Corrige

This section described the changes that have to be applied to the D 3.9.1 Appendix B1 [D3.9.1 B1] specification.

## 3.1 1.3.6.1.4.1.19376.1.5.3.1.4.5 epSOSCodeProb binding

### 3.1.1 Description

There is an incoherency between the requirement of using the epSOSCodeProb (1.3.6.1.4.1.12559.11.10.1.3.1.42.23) Value Set in the 1.3.6.1.4.1.19376.1.5.3.1.4.5 template and the usage of the epSOSAdverseEventType for allergies.

In fact the template Allergies and Intolerances 1.3.6.1.4.1.19376.1.5.3.1.4.6 specializes the IHE PCC Problem Entry 1.3.6.1.4.1.19376.1.5.3.1.4.5. Therefore, if we restrict the binding of the xx.1.4.5's observation/code element to epSOSCodeProb value set this is inherited also by the 1.4.6's observation/code.

The keyword is SHOULD and not SHALL.

The SHALL binding with epSOSCodeProb has to be applied when this observation is used within the Problem Concern Entry 1.3.6.1.4.1.19376.1.5.3.1.4.5.2.

### 3.1.2 Original Text

Pag 157. § 13.1.6.14.7. “Description of the problem”

“The required (only recommended for the IHE template) vocabulary for describing problems is Value set epSOSCodeProb, OID 1.3.6.1.4.1.12559.11.10.1.3.1.42.23”

### 3.1.3 Amended Text

“The recommended vocabulary for describing problems is Value set epSOSCodeProb, OID 1.3.6.1.4.1.12559.11.10.1.3.1.42.23.

This value set is required in epSOS when used within the Problem Concern Entry 1.3.6.1.4.1.19376.1.5.3.1.4.5.2”

## 3.2 Fixed Typos

| **Page** | **§** | **Original Text** | **Amended Text** |
|---|---|---|---|
| 83 | 11.1.2.2 | Even if no one of the allowable relationship defined by the CDA standard (XFRM, RPLC, APDN) fits perfectly with the relationship existing between the pivot and the PDF CDA; the APND relationship seems to be that better describing the epSOS scenario. | “Even if no one of the allowable relationship defined by the CDA standard (XFRM, RPLC, APND) fits perfectly with the relationship existing between the pivot and the PDF CDA; the APND relationship seems to be that better describing the epSOS scenario.” |
| 83 | 11.1.2.2 | <relatedDocument typeCode="APDN" ><br><parentDocument><br><id root="aa1-bb1-cc1" /><br></parentDocument><br></relatedDocument> | <relatedDocument typeCode="APND" ><br><parentDocument><br><id root="aa1-bb1-cc1" /><br></parentDocument><br></relatedDocument> |
| 30 | 10.1 R1.10.5 | (cardinality ) [1..] | (cardinality ) [1..*] |
| 30 | 10.1 R1.10.6 | (cardinality ) [1..*] | (cardinality ) [1..1] |
| 38 | 10.1 R1.11.9 | (cardinality ) [1..*] | (cardinality ) [1..1] |

| Page | § | Original Text | Amended Text |
|---|---|---|---|
| 49 | 11 R4.7 | epSOSRoutesofAdministration | epSOSRouteofAdministration |
| 52 | 11 R4.9 | 1.3.6.1.4.1.12559.11.10.1.3.1.3.4 | 1.3.6.1.4.1.12559.11.10.1.3.1.3.2 |
| 159 | 13.1.6.14.14 | epSOSstatusCode | epSOSStatusCode |
| 167 | 13.1.12.7 | <templateId root='2.16.840.1.113883.10.20.1.33/> | <templateId root='2.16.840.1.113883.10.20.1.33'/> |
| 172 | 13.1.14.3.5 | code='46680005 ' | code='46680005' |
| 173 | 13.1.14.3.5 | codeSystemName=' SNOMED CT' | codeSystemName='SNOMED CT' |
| 177 | 13.1.15.1.1.4 | "The organizer shall..." | "The observation shall..." |
| 108 | 12.1.2.4.3 | </substanceAdministation> | </substanceAdministration> |
| 152 | 13.1.6.3.3 row 2669 | <observation classCode='OBS' moodCode='EVN'/> | <observation classCode='OBS' moodCode='EVN'> |
| 152 | 13.1.6.3.5 row 2690 | <templateID root='1.3.6.1.4.1.19376.1.5.3.1.4.5'> | <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5' /> |

## 3.3 Clean-up of references to the “Current History of Present Illness” Section

### 3.3.1 Description

It was clarified that coded current problems are expected to be found in the Active Problem Section. The § 11 Table (Pag 68 R11.1 and Pag 69 R11.2) still includes references to the **History of Present Illness Section.**

Remove references to **History of Present Illness Section** in this table.

Moreover TXT needs to be changed into ST, other minor issues needs to be fixed

### 3.3.2 Original Text

| | | | | | | |
|---|---|---|---|---|---|---|
| R11.1 | Problem/diagnosis description (Problem/ diagnosis description) | **1.3.6.1.4.1.19376.1.5.3.1.3.4** **History of Present Illness Section** Narrative section section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.4']/text | | NA / NA / RNFA | TXT | |
| | | **1.3.6.1.4.1.19376.1.5.3.1.3.6** **Active Problems Section** | **1.3.6.1.4.1.19376.1.5.3.1.4.5.2** **Problem Concern Entry** entry/act[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2']/ entryRelationship[@typeCode='SUBJ']/ observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5']/value/@displayName | | TXT | |

AND

| | | | | | | |
|---|---|---|---|---|---|---|
| R11.2 | Problem Code (Problem Id code) | **1.3.6.1.4.1.19376.1.5.3.1.3.6** **Active Problems Section** | **1.3.6.1.4.1.19376.1.5.3.1.4.5.2** **Problem Concern Entry** entry/act[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2']/ entryRelationship[@typeCode='SUBJ']/ observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5']/value/@code | NA / NA / RNFA | CD | epSOSIllnessesandDisorders 2.16.840.1.113883.6.90 |
| | | **1.3.6.1.4.1.19376.1.5.3.1.3.4** **History of Present Illness Section** | Same as above | | | |

### 3.3.3 Amended Text

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **R11.1** | **Problem/diagnosis description (Problem/diagnosis description)** | | | **1.3.6.1.4.1.19376.1.5.3.1.3.6 Active Problems Section** | **1.3.6.1.4.1.19376.1.5.3.1.4.5.2 Problem Concern Entry** entry/act[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2']/ entryRelationship[@typeCode='SUBJ']/ observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5']/value/@displayName | NA / NA / RNFA [1..1] | ST | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **R11.2** | **Problem Code (Problem Id code)** | **1.3.6.1.4.1.19376.1.5.3.1.3.6 Active Problems Section** | **1.3.6.1.4.1.19376.1.5.3.1.4.5.2 Problem Concern Entry** entry/act[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2']/ entryRelationship[@typeCode='SUBJ']/ observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5']/value/@code | NA / NA / RNFA | CD | epSOSIllnessesandDisorders 2.16.840.1.113883.6.90 |

## 3.4 Substance Administration id Nullflavor allowed

### 3.4.1 Description

There are comments about the fact that the section 12.1.1.2.4.2.1 Substance Administration ID could be misleading in terms of nullFlavor usage.

Waiting for a more formal specification of the conformance assertions, a clarification on this subject should be added.

### 3.4.2 Original Text

A top level <substanceAdministration> element must be uniquely identified. This can be the prescription item ID if appropriate.

### 3.4.3 Amended Text

A top level <substanceAdministration> element must be uniquely identified. This ID shall not be nullflavored when used for identifying the prescription item ID within the Dispensed Medicine Entry Content Module (1.3.6.1.4.1.12559.11.10.1.3.1.3.3) and the “Prescription Item Entry Content Module” (1.3.6.1.4.1.12559.11.10.1.3.1.3.2); it might be valorized with an appropriate nullflavor in all the other cases.

# 4 Known Issues

This section summarizes the issues known about the D 3.9.1 Appendix B1 [D3.9.1 B1] specification, that need to be addressed.

## 4.1 Improve the CDA specifications clarity.

### 4.1.1 Description

Different perspectives (end users, architects, developers) are sometimes mixed up in the current specifications, making them sometime not so clear to the reader.

### 4.1.2 Change Proposal

Separate all those perspectives in different artifacts:

1. Refined conceptual model
2. Refined to Implementation model mapping
3. Implementation specification

Use a formal specification language for the template implementation.

The adoption of DÉCOR is under evaluation.

## 4.2 Not Known Allergy

### 4.2.1 Description

The epSOS approach for describing the absence of allergy are based on previous IHE PCC versions that required to express the absence of known allergy using the "No known Allergies" code.
“The coded form shall be used to indicate "No known Allergies" (code='160244002' codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CD').”
The interpretation done was that either the allergy or the "No known Allergies" information shall be provided.
Basing on the epSOS experiences and the current IHE PCC template definition “The allergy or intolerance may not be known, in which case that fact shall be recorded appropriately. “ we need to revise this approach.

### 4.2.2 Change Proposal

Clarify in the text that if the assertion “No Known Allergies” is applicable this code shall be used, otherwise other suitable solution (e.g NullFlavor = ‘NI’) can be adopted.

Add some examples

Other Task: check the impact on the current implementations.

## 4.3 Blood Group (Coded Results Section 1.3.6.1.4.1.19376.1.5.3.1.3.28)

### 4.3.1 Description

There is a formal inconsistency between the epSOS template Coded Results Section and the IHE PCC is derived from.

The epSOS template is designed having in mind the CCD Result template (2.16.840.1.113883.10.20.1.14) but it refers the IHE PCC coded result section template that requires the procedure entry.
This has not a direct impact on the current epSOS pilot neither on the patient safety, being used only for conveying the blood group result.

### 4.3.2 Change Proposal

Two options are possible:

1. Refer the CCD template
2. Add the Procedure Entry

This change could be postponed at the end of the project in order to not impact on current pilot. The best solution is to adopt the second option being the same used for the Consolidated CDA.

## 4.4 Procedures and Interventions Section

### 4.4.1 Description

The D 3.9.1 B1 includes the description of the 1.3.6.1.4.1.19376.1.5.3.1.1.13.2.11 “Procedures and Interventions “ section . This should be used for describing the procedures performed during the encounter.
This section is not used for conveying information included in the basic and/or extended PS data set, and confused the reader.

### 4.4.2 Change Proposal

Remove this section description in the specification.

## 4.5 Not Applicable/Not known Procedures

### 4.5.1 Description

The 3.9.1 asserts that “Each surgical procedure shall be described using the “Procedure Entry” template (1.3.6.1.4.1.19376.1.5.3.1.4.19).
In case no procedures are expected to be recorded, a single “NA” nullFlavored procedure entry shall be included in this section.”

The correct formal interpretation of this rule is to provide a single 1.3.6.1.4.1.19376.1.5.3.1.4.19 NA nullflavored Procedure Entry: that means that (therefore with the suitable nullflavored sub-elements provided).

```
<procedure classCode='PROC' moodCode='EVN' nullFlavor='NA' >
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.19'/>
  <templateId root='2.16.840.1.113883.10.20.1.29'/>
  <id nullFlavor='NI'/>
  <code nullFlavor='NI'/>
  <text><reference value='#xxx'/></text>
  <statusCode nullFlavor='NI'/>
</procedure>
```

For facilitating the pilot implementation this has been interpreted as provide a single NA nullflavored procedure entry.

### 4.5.2 Change Proposal

Make this assertion more explicit

Additional Tasks: check the validators behavior.

## 4.6 Medical Devices

### 4.6.1 Description

The 3.9.1 asserts that
“Each devices shall be described using the “Medical Devices Entry Content Module” template (1.3.6.1.4.1.12559.11.10.1.3.1.3.5).
In **case no devices or implants are expected to be recorded**, a single “NA” nullFlavored supply entry shall be included in this section.”

The correct formal interpretation of this rule is if there are no devices implanted you can assert this with a single 1.3.6.1.4.1.12559.11.10.1.3.1.3.5 NA nullflavored supply Entry: for example.

```
<supply moodCode="EVN" classCode="SPLY" nullFlavor='NA'>
   <templateId root="1.3.6.1.4.1.12559.11.10.1.3.1.3.5"/>
   <text><reference value="#DevDescr"/></text>
   <effectiveTime nullFlavor='NI'/>
   <participant typeCode="DEV">
      <participantRole classCode="MANU">
         <playingDevice classCode="DEV" determinerCode="INSTANCE">
            <code nullFlavor='NI'/>
         </playingDevice>
      </participantRole>
   </participant>
</supply>
```

If you have no idea if devices have been implanted or not the way to do it is a single 1.3.6.1.4.1.12559.11.10.1.3.1.3.5 NI nullflavored supply Entry: for example.

```
<supply moodCode="EVN" classCode="SPLY" nullFlavor='NI'>
   <templateId root="1.3.6.1.4.1.12559.11.10.1.3.1.3.5"/>
   <text><reference value="#DevDescr"/></text>
   <effectiveTime nullFlavor='NI'/>
   <participant typeCode="DEV">
      <participantRole classCode="MANU">
         <playingDevice classCode="DEV" determinerCode="INSTANCE">
            <code nullFlavor='NI'/>
         </playingDevice>
      </participantRole>
   </participant>
</supply>
```

Moreover, basing on the conceptual model there are only two elements required (nullflavor allowed)

1. The device code/description => /participantRole/playingDevice/code
2. The Device Implant Date => entry/supply[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.5']/effectiveTime

This is not so clear form the entry template description in the § 13.1.8.3.12.1.8.3. Medical Devices Entry Content Module 1.3.6.1.4.1.12559.11.10.1.3.1.3.5; doesn't use the conformance keywords SHALL/SHOULD/MAY.

### 4.6.2 Change Proposal

Make the entry template description more clear (using conformance keywords).

Make more explicit how to assert the absence of  information

Additional Tasks: check the validators behavior.

## 4.7 Language Communication

### 4.7.1 Description

The Language Communication template 1.3.6.1.4.1.19376.1.5.3.1.2.1 requires that the preferenceInd (values true or false) subelement is present within the languageCommunication.
This is not explicitly declared in the specification (unless the reference to the xxx.1.2.1 template).
Clarify this point

### 4.7.2 Change Proposal

To be decided if maintain the compliance with the template or not .

Suggestion : keep the compliance with the Language Communication template and add a note.

## 4.8 Brand Name (vaccines)

### 4.8.1 Description

The current specification uses two different approaches for describing the Brand Name product for medications (MMAT.name) and the vaccines (MMAT.code.translation@displayName).
Considering that in epSOS the translation attribute is used for recording the translated designation this choice leads to some problem on displaying the PS.

### 4.8.2 Change Proposal

Align the vaccination approach with the medication one.

## 4.9 Legal Authentication

### 4.9.1 Description

To be investigated the actual meaning of the LegalAuthentication element of a transformed document; and how to handle the ”original” Legal Authenticator.

### 4.9.2 Change Proposal

No changes planned.
To be considered for future evolutions

## 4.10 Section Code and title

### 4.10.1 Description

Current MVC /MTC includes only the list of section LOINC codes and their translation. These concepts even if coherent with the contents defined by the WP 3.1 doesn't exactly fit with what HPs expect to see. For example they like to see "Medical devices" instead of "History of medical device" and so on.. This "expectation" is in line with the CDA standard, where the section code is used to classified the section but what is displayed to human is the section title (that shall be non in contrast with the section code). This is also a CDA display related issue.

To fix this issue in the epSOS environment we need:

1) Define a new Value Set for the section titles: this VS should allow to link the section template ID and the section labels to be shown.
2) Evaluate if it's worth to leave the responsibility of showing the translated label to the display system either we want to update the section <title> in order to allow even to not epSOS aware display to show the translated information

The Clinical Experts Team analyzed this issues and identified the appropriated names that should be shown to the end users.

### 4.10.2 Change Proposal

No changes planned.

To be considered for future evolutions

## 4.11 Distinction between coding of medicine on a brand-level and on package-level

### 4.11.1 Description

The current specification does not distinguish between the coding of medicine on a brand-level (e.g. ASPIRINA) and coding on package-level (e.g. "ASPIRINA C*10CPR EFF 400+240MG"). (issue risen by ELGA).

### 4.11.2 Change Proposal

No changes planned.

To be considered for future evolutions if we suppose to align the epSOS specification with the IHE Pharmacy choices.

## 4.12 CapacityQuantity vs Quantity

### 4.12.1 Description

Current specification uses the /containerPackagedMedicine/capacityQuantity element to describe the Package Size (e.g. the number of tablets in a package). From the model point of view this attributes describes the capacity of a container (e.g number of pills that a box may include) where effective quantity of medicines is described by the asContent/quantity element. In most cases these two quantities are coincident.

### 4.12.2 Change Proposal

No changes planned.

To be considered for future evolutions.

## 4.13 Supply / substance administration quantity attribute

### 4.13.1 Description

Due to the well-known ambiguity of the supply / substance administration quantity attribute, a revision of the usage of the quantity related attributes may be done according to possible wider agreed interpretations (see for example the choices made by the IHE Pharmacy group).

### 4.13.2 Change Proposal

No changes planned.

To be considered for future evolutions if we suppose to align the epSOS specification with the IHE Pharmacy choices.

## 4.14 Observation code (substitution)

### 4.14.1 Description

The substitution act for prescription is described using an observation, this choice does not requires CDA extensions. The Pharmacy model uses instead a SUBST act (this requires a CDA extension).

### 4.14.2 Change Proposal

No changes planned.

To be considered for future evolutions if we suppose to align the epSOS specification with the IHE Pharmacy choices.

# 5 References

## 5.1 Normative References

[D3.9.1 B1] Work Package 3.9 – Appendix B1/B2 epSOS Semantic Implementation Guidelines.

[CDAR2] CDA® Release 2 (http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7 )

## 5.2 Non-Normative References

[CCDA] US Realm Consolidated[3] CDA specifications (http://www.hl7.org/implement/standards/product_brief.cfm?product_id=258)

## 5.3 Open Source Solutions (non-normative)

Not Applicable.

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