NHS Connecting for Health	**SCG Guidance on the Representation of Allergies and Adverse Reaction Information Using NHS Message Templates**			
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SCG Guidance on the Representation of Allergies and Adverse Reaction Information Using NHS Message Templates

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All system suppliers building functionality to support clinical message domains

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Related Documents:

These documents will provide additional information.

Ref no	Doc Reference Number	Title	Version
1	NPFIT-SHR-QMS-PRP-0015	Glossary of Terms Consolidated.doc	13
2	NPFIT-FNT-TO-DPM-0737	NPFIT-ELIBR-AREL-P1R2-0178 Technical Guidance for Implementation of Templated CDA Domains	1.1
3	NPFIT-EP-DB-0007	Representation in Electronic Patient Records of Allergic Reactions, Adverse Reactions, and Intolerance of Pharmaceutical Products	1.5
4		SNOMED CT User Guide	20070731

Glossary of Terms:

List any new terms created in this document. Mail the NPO Quality Manager to have these included in the master glossary above [1].

Term	Acronym	Definition
Clinical Document Architecture	CDA	An XML vocabulary designed to provide an exchange model for clinical documents such as discharge summaries and progress notes
Message Implementation Manual	MIM	Manual providing information for messaging requirements for implementation
Care Record Element	CRE	
X_domain		A HL7 term for a subset of an HL7 vocabulary code list
NHS CFH Templated Domain		A NHS CFH MIM domain which has HL7 RMIMs which utilise the NHS CFH templates
Systemized Nomenclature of Medicine Clinical Terms	SNOMED CT	A single unified terminology to underpin the development of the integrated electronic patient record by providing an essential building block for a common computerized language for use across the world.
Common Message Element Type	CMET	Intended to express a common, reusable pattern
Refined Message Information Model	RMIM	HL7 model derived from the HL7 RIM
Reference Information Model	RIM	The RIM covers all entities and data elements about which HL7 messages communicate

NHS Message Template		A template is a RMIM which is used to constrain another model
Participation		The involvement of a role in an act
actRelationship		A relationship between two acts
Class clone		A class that is a clone of another class, derived from another class
Act		Something happened or may happen
Entity		A person, animal, organisation or thing
Role		A responsibility or part played by an entity
Transform (XSLT)		A language for transforming XML
On the Wire Format		Actual XML instance with CDA balloted class names that will flow on the wire and be stored on PSIS and other systems
Ballot or Balloted		HL7 Clinical Document Architecture, Release 2.0 (2006 Normative Edition)
MIF		An HL7 model in an XML format.
NHS Dictionary of Medicines and Devices	NHS dm+d	The dm+d is a vocabulary dictionary containing unique identifiers and associated textual descriptions for medicines and medical devices.
Personal Spine Information Service	PSIS	The PSIS will be the central database containing clinical records on each NHS patient. The PSIS record provides an up to date summary of information and key events in a patients life and care, drug allergies, operations, conditions, medication history – as well as details of contacts with care providers.
Adverse Drug Reaction	ADR	Expression that describes the unwanted, negative consequences associated with the use of given medications. An ADR is a particular type of adverse effect. The meaning of this expression differs from the meaning of "side effect", as this last expression might also imply that the effects can be beneficial

Contents

1 Purpose

This guidance is designed to provide detailed technical information on the representation of allergies and adverse reactions when using NHS message templates.

This guidance is aimed at the MIM 6.0301 clinical domains, i.e. Inpatient Discharge, Emergency Department and Outpatient sections of the Personal Spine Information Service (PSIS) Clinical Document Architecture.

N.B. Where a HL7 RMIM / model or any other Message Implementation Manual (MIM) artefact is shown this may not be the latest version of that artefact and the relevant version of the MIM should be consulted for the actual artefact version to implement.

Due to the complexity of diagrams contained within this document it is recommended the reader views the document at 150% or larger.

1.1 Definitions

Where used in this document set, the keywords **must**, **should**, **may**, **must not** and **should not** are to be interpreted as described in RFC 2119.[1]

- **Must**: This word, or the terms "**required**" or "**shall**", means that the definition is an absolute requirement of the specification
- **Should**: This word, or the adjective "**recommended**", means that there may exist valid reasons in particular circumstances to ignore a particular item, but the full implications **must** be understood and carefully weighed before choosing a different course.
- **May**: This word, or the adjective "**optional**", means that an item is truly optional. One implementer may choose to include the item because a particular implementation requires it, or because the implementer feels that it enhances the implementation while another implementer may omit the same item. An implementation which does not include a particular option **must** be prepared to interoperate with another implementation which does include the option, perhaps with reduced functionality. In the same vein, an implementation which does include a particular option **must** be prepared to interoperate with another implementation which does not include the option (except of course, for the feature the option provides).
- **Must not**: This phrase, or the phrase "**shall not**" mean that the definition is an absolute prohibition of the specification.
- **Should not**: This phrase, or the phrase "**not recommended**" mean that there may exist valid reasons in particular circumstances when the particular behaviour is acceptable or even useful, but the full implications **should** be understood and the case carefully weighed before implementing any behaviour described with this label.

[1] http://www.faqs.org/rfcs/rfc2119.html

1.2 Further Enquiries

Enquiries about the contents of this document, or any of the requirements within it should be sent to nhscfh.scg@nhs.net.

The Standards Consulting Group (SCG) information is posted at http://www.connectingforhealth.nhs.uk/systemsandservices/data/scg.

2 Audience

This guidance is aimed at all system suppliers building functionality to produce and/or receive messages for the PSIS CDA domain in 2008-A, these being Discharge Summary, Emergency Department and Outpatient.

3 Background

The message template mechanism used with the NHS CFH templated CDA implementation is based on the modular approach first used in GP Summary (MIM 4.2). This was developed to tighten the rules and dependencies around the use of Care Record Element types (CRE), Common Message Element Types (CMETs) and SNOMED CT Subsets. This mechanism provides a better, more consistent approach that is easier to implement.

The message templates used in the CDA implementation take the place of the CMETs used in GP Summary and although the approach differs somewhat the aim is still the same.

Using message templates allows for greater extensibility and consistency of the messages / documents than CMETs allowed.

A library of message templates will be maintained by NHS CFH to meet new requirements and will be published in the MIM.

The same templating mechanism is used in both CDA and non-CDA based domains (that utilise the NHS CFH templates) and therefore this guidance document applies equally to message template usage in both styles of interaction.

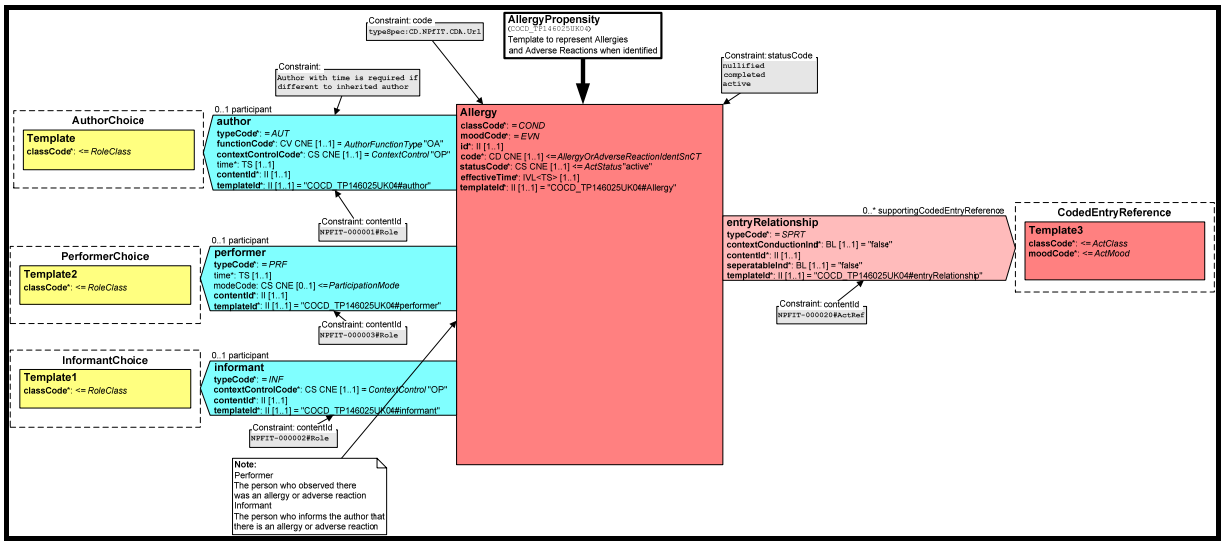
4 Representations of Allergies and Adverse Reactions

This guidance is based on “Representation in Electronic Patient Records of Allergic Reactions, Adverse Reactions, and Intolerance of Pharmaceutical Products” version 1.5 NPFIT-EP-DB-0007. For the avoidance of doubt if there is any discrepancy between the above document and the guidance below then the guidance below, should be followed.

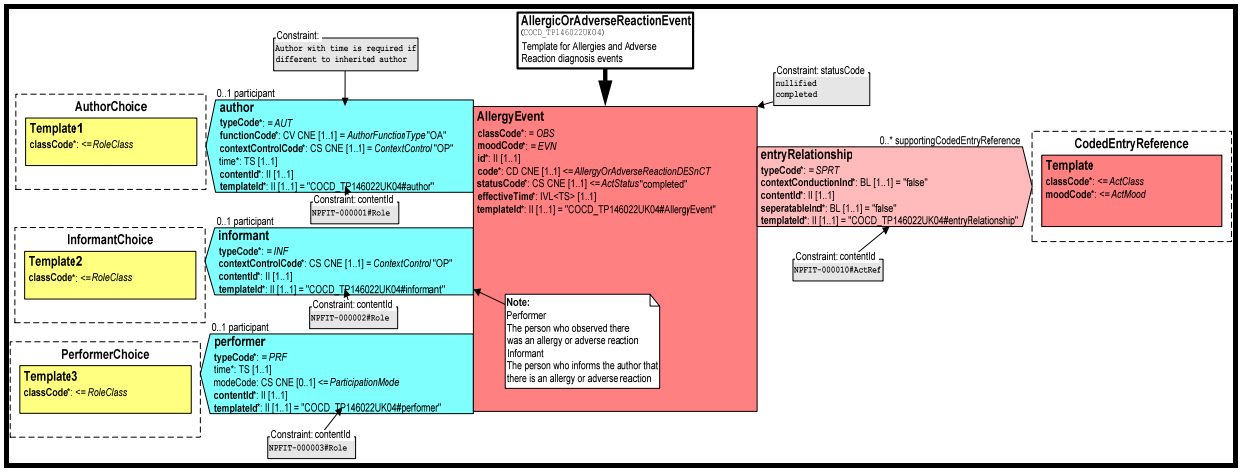
The representation of allergies is achieved using two templates:

- AllergyPropensity
- AllergicOrAdverseReactionEvent.

4.1 AllergyPropensity template



4.2 AllergicOrAdverseReactionEvent template



It is important to distinguish between two kinds of allergic reaction / adverse reaction entry in the medical record:

- Recording an Allergic Response or Adverse Reaction to an item of medication or a substance
- Recording a clinician's opinion about future risk of (or propensity to) an Allergy or other Adverse Reaction if the patient is exposed to a substance.

The allergy propensity template is used to populate the patients' allergy and adverse reactions list. This is a list of all the substances/drugs/food that a person is at future risk of having an adverse reaction or allergy to. Ideally there **should** be only one entry per drug/substance/food/causative agent.

e.g.

A patients' Allergy/Adverse Drug Reaction (ADR) Propensity list could consist of

12 Jan 2006	Allergy to penicillin
13 Feb 2003	Allergy to peanuts
06 Mar 1999	Allergy to wasp sting

Not

12 Jan 2006	Allergy to penicillin
14 Jul 2005	Allergy to peanuts
18 Feb 2004	Allergy to peanuts
13 Feb 2003	Allergy to peanuts
06 Mar 1999	Allergy to wasp sting

In this respect the causative agent code **should not** be duplicated. It is acceptable to have entries for causative agents which are similar, e.g. penicillin and amoxicillin, but have different causative agent codes.

Systems **should** prompt users if adding allergy propensities with duplicate causative agent codes.

The system **should** record an allergy event recording for each allergy event that the patient suffers.

- If a patients' record has an AllergyOrAdverseReactionEvent statement then they **should,** in most cases also have one corresponding AllergyPropensity-statement. It is a clinical judgement as to whether this occurs. It may be reasonable to not have a corresponding allergy propensity if the allergy event is not certain.
- However if a patients' record has a AllergyPropensity - statement it is **not required** for there to be a corresponding AllergyOrAdverseReactionEvent - statement
- A patients' record **should** only have one AllergyPropensity - statement to the same drug, food or substance.

Most existing systems will not currently support Allergy/ADR propensity and event split. When this is the case then it is expected that systems publish AllergyPropensity for all allergy and adverse reaction records which it holds. This may result in duplication of allergy records which would ideally be rectified (if there are 2 entries which have the same causative agent code then the entry with the earliest date should be sent).

4.3 Decision Support Implication

Whilst a high level aim of a standardised Allergy and ADR representation is to support Clinical Decision Support (CDS), this aim can not always be met. In

particular the causative agent chosen by the user may not always be one which has the capability to trigger decision support. This is likely to be the case for some time.

4.4 Population of the act.code

Population of the act.code is achieved using a post coordinated SNOMED CT phase.

This phrase is made up of an “event” or “condition” code which is qualified by a causative agent attribute and an “agent” code.

The “event” or “condition” describes the type of reaction and the type of causative agent.

e.g. “drug allergy” or “propensity to adverse reaction to food”

The “agent” code identifies the specific causative agent.

The expressions below would be represented by the general HL7 Clinical Data (CD) pattern.

```
<code code="CONCEPTID" displayName="[EVENT OR CONDITION]">
 <qualifier>
  <name code="246075003" displayName="causative agent" />
  <value code="CONCEPTID" displayName="[AGENT]" />
 </qualifier>
</code>
```

The data type CD must be populated using one of the following patterns (**N.B.** reference value is shown for completeness only) and all patterns use “on the wire” format

Standard Pattern – without context model

```
<code code=" [EVENT or CONDITION - concept ID] " codeSystem="2.16.840.1.113883.2.1.3.2.4.15" displayName="
[EVENT or CONDITION code display name] ">
<originalText>
        <reference value="#a1"/>
</originalText>
<qualifier>
   <name code="246075003" displayName="causative agent" />
   <value code=" [AGENT concept ID] " displayName=" [AGENT code displayName] " />
      </qualifier>
</code>
```

Standard Pattern – with context model

```
<code code="243796009" codeSystem="2.16.840.1.113883.2.1.3.2.4.15" displayName="situation with explicit context">
<originalText>
        <reference value="#a1"/>
</originalText>
<qualifier>
<name code="246090004" displayName="associated finding"/>
  <value code="[EVENT or CONDITION - concept ID]" displayName=" [EVENT or CONDITION code display name] ">
    <qualifier>
      <name code="246075003" displayName="causative agent" />
      <value code="[AGENT concept ID]" displayName="[AGENT code displayName]? />
    </qualifier>
  </value>
</qualifier>
<qualifier>
 <name code="408729009" displayName="finding context"/>
 <value code=" [FINDING CONTEXT VALUE concept ID]" displayName=" [FINDING CONTEXT VALUE display name] "/>
</qualifier>
</code>
```

Standard Pattern – with context model and severity

```
<code code="243796009" codeSystem="2.16.840.1.113883.2.1.3.2.4.15" displayName="situation with explicit context">
<originalText>
        <reference value="#a1"/>
</originalText>
<qualifier>
<name code="246090004" displayName="associated finding"/>
  <value code="[EVENT or CONDITION - concept ID]" displayName=" [EVENT or CONDITION code display name] ">
    <qualifier>
      <name code="246075003" displayName="causative agent" />
      <value code="[AGENT concept ID]" displayName="[AGENT code displayName]" />
    </qualifier>
     <qualifier>
      <name code="246112005" displayName="Severity" />
      <value code="[SEVERITY VALUE concept ID]" displayName="[SEVERITY VALUE displayName]" />
    </qualifier>
  </value>
</qualifier>
<qualifier>
 <name code="408729009" displayName="finding context"/>
 <value code=" [FINDING CONTEXT VALUE concept ID]" displayName=" [FINDING CONTEXT VALUE displayName] "/>
</qualifier>
</code>
```

4.5 Pre-coordinated Codes

It is possible to record allergies using SNOMED CT in a precoordinated or post coordinated form. While both methods of recording allergies are possible, the handling of the allergy codes by systems **must** follow the post-coordinated model. The only exception is where systems contain legacy data (see below).

Current systems **may** contain allergies entries which are recorded against pre-coordinated allergy or adverse reaction codes. This could be in either Read codes (Read 2 or CTV3) or SNOMED CT.

e.g.

14L1. H/O Penicillin allergy (Read 2)

Xa5sH Penicillin allergy (CTV3)

91936005 penicillin allergy (SNOMED CT)

There is currently no mapping available from all of these pre-coordinated codes to the post-coordinated form.

Suppliers have a number of options when populating these codes into messages.

Option 1

Map these codes to the post-coordinated form. Mapping tables will need to be developed by the supplier. Details of the mapping tables will need to be provided to the authority for validation.

Option 2

Populate the act.code with a single pre-coordinated code. **N.B.** Read or CTV3 codes will require mapping to SNOMED CT. (e.g. pre-coordinated Read to pre-coordinated SNOMED CT).

4.6 Certainty and Severity and Other Qualifiers

Systems **may** allow the recording of qualifiers against allergy and adverse reaction entries. These qualifiers need to be carefully handled.

1. Ideally AllergyPropensity **should not** be modified with certainty or severity. It is understood however that legacy data may have included such modification, if so this should be carried either as text or post coordinated SNOMED CT (see above and below for further guidance)
2. Qualifiers **may** be degraded to text if the qualifiers do not negate an allergy/ADR record
3. If a record is negated by a qualifier e.g. by using a qualifier such as “definitely not present”. Then this record **should not** populate a message
4. Some qualifiers **may** require specific analysis – suppliers are **required** to declare, as part of the assurance process, which qualifiers they currently allow against entries.

Use of the SNOMED CT Context model (see SNOMED Documentation – SNOMED CT User Guide 20070731 section 4.8) is allowed (***optional***); however only the use of findings context is appropriate.

The table below details the finding context qualifiers available in SNOMED CT (descendants of 410514004|finding context value). Of these some do not express certainty so **must not** be used e.g. goal. Others significantly negate the allergy/ADR record so **must not** be used.

This leaves 4 values:

- Probably present
- Suspected
- Definitely present
- Confirmed present.

Any other values **must not** be used.

4.7 Analysis of Findings Context Values

Concept ID	Preferred Term	Certainty yes/no	Use with allergies/ADRs
410519009	at risk	no	no
410517006	expectation	no	no
410596003	likely outcome	no	no
71033007	impending	no	no
410595004	prognosis context	no	no
410518001	goal	no	no
36692007	known	yes	no
410516002	Known absent	yes	no
410594000	definitely not present	yes	no
410593006	probably not present	yes	no
410590009	Known possible	yes	no
410592001	probably present	yes	yes
415684004	suspected	yes	yes
410515003	known present	yes	no
410591008	definitely present	yes	yes
410605003	confirmed present	yes	yes

4.8 Substance, Food and Drug

Entries for allergy/ADR propensity and events need to be categorised by type of causative agent. Each category has separate “event” or “condition” codes and uses different causative agent constraints.

4.9 Specific Code Constraints

The following tables define the allowable coded expressions:

Note – The codes below are subject to change in subsequent SNOMED CT Releases. If this occurs replacement for any retired codes will be included in the updated subsets.

Template	MIM Vocab	MIM Vocab (2)	Subset ID	EVENT or CONDITION Code	Allowable AGENT Codes
AllergyPropensity (COCD_TP146025UK04)	AllergyOrAdverseReactionIdentSnCT	AllergyIdentSnCT	**1101000000130**	416098002 Drug allergy (disorder)	DRUG
				419199007 Allergy to substance (disorder)	DRUG or FOOD or NON FOOD
				414285001 Food allergy (disorder)	FOOD
		AdverseReactionIdentSnCT	**1011000000131**	419511003 Propensity to adverse reactions to drug (disorder)	DRUG
				418038007 Propensity to adverse reactions to substance (disorder)	DRUG or FOOD or NON FOOD
				418471000 Propensity to adverse reactions to food (disorder)	FOOD
			Code will be included in Propensity to adverse reaction subset in the next TRUD (April 2008)	59037007 Drug intolerance (disorder)	DRUG

Template	MIM Vocab	MIM Vocab (2)	Subset ID	EVENT or CONDITION Code	AGENT Codes Allowable
AllergicOrAdverseReactionEvent (COCD_TP146022UK04)	AllergyOrAdverseReactionDESnCT	AllergyDESnCT	**1111000000132**	416093006 Allergic reaction to drug (disorder)	DRUG
				241937000 Drug-induced anaphylaxis (disorder)	DRUG
				241947002 Drug-induced anaphylactoid reaction (disorder)	DRUG
				419452009 Allergic reaction to food (disorder)	FOOD
				418634005 Allergic reaction to substance (disorder)	DRUG or FOOD or NON FOOD
		AdverseReactionDESnCT	**1021000000139**	62014003 Adverse reaction to drug (disorder)	DRUG
				282100009 Adverse reaction to substance (disorder)	DRUG or FOOD or NON FOOD
				370540009 Adverse reaction to food (disorder)	FOOD

Agent Constraints

Agent constraints are **not** mandated. It is allowable to use codes outside the constraints; however the notes regarding CDSS (in section 5.1 above) **should** be noted.

Drug Constraint (**drug**) codes from the following

NHS dm+d[2] AMP

Or

NHS dm+d VMP

Or

NHS dm+d VTM

Or

Drug Categories subset original ID 7851000000131

Note

The Drug - allergy and adverse reaction constraint subset original ID 1081000000138 has now been replaced by the Drug Categories subset.

Food Constraint (**food**) codes from the following

Food allergens subset original ID 2001000000137

Non Food Constraint (**non food**) codes from the following

Non-food substance allergens subset original ID 1991000000135

It should be noted that there is overlap of content between the subsets used for food, non food and drug. E.g. it is entirely reasonable for a food to be an ingredient of a drug. CDS systems should be aware of this when deciding which allergy records to involve in CDS processes.

4.10 Use of CRETypes with Allergies and Adverse Reactions

163001000000103	diagnoses - care record element (administrative concept)

This CRE type **should** be used when recording an Adverse Reaction or Allergic Response to an item of medication or a substance using the Allergic or Adverse Reaction Event template.

163221000000102	allergies and adverse reactions - care record element (administrative concept)

This CRE type **should** be used when recording a clinician's opinion about future risk of (or propensity to) an Allergy or other Adverse Reaction if the patient is exposed to an item of medication or a substance.

[2] http://www.dmd.nhs.uk/

4.11 Receiving System Processing Rules

When a system retrieves a document from the PSIS there are a number of options available.

1. The system **must** render the document for reading by a human user. The guidance on use of style sheets, previously documented in the Technical Guidance for Implementation of Templated CDA Domains NPFIT-FNT-TO-DPM-0737 (section 2.4.1.2), **must** be followed.
2. When receiving an allergy/ADR record the system **may** allow this record to be incorporated into the local record. The clinical user **must** always authorise this process.
3. The receiving system **must** be able to fully process all semantics contained in a template in order to safely incorporate the clinical information into the system. For example, if a system, which can not process information held in the SNOMED CT Context model, receives a message that contains SNOMED CT context, then the information held in this template **must not** be incorporated into the receiving system.

4.12 Allergy No Longer Present

The current guidance rules out the representation of allergy no longer present or patient no longer has allergy as a codified statement. The current architecture (PSIS and Point to Point Messages) does not support automatic information updates between messages. If in a care episode a clinician decides that a patient no longer has an allergy which had previously been identified, then an update would be made to the local system. The clinician would then include the fact that this decision had been made and the reasons for it in the text of the document. The document **should** include a specific request to the GP to remove[3] this allergy from the GP system and hence the GP summary.

[3] By remove we mean to mark the record as no longer being true for the patient and removing the item from a list of current allergies. The original entry would be retained as part of the audit log.

A Appendix 1 – Additional Reference Materials

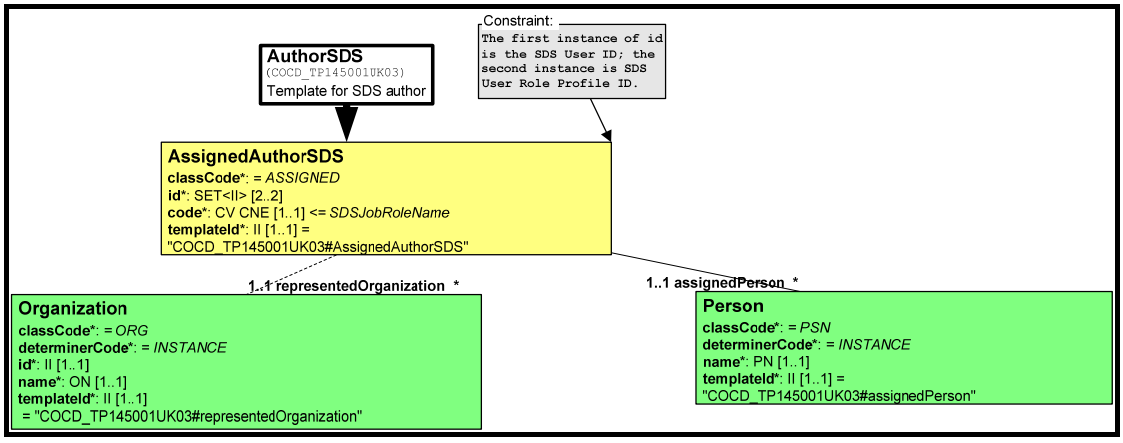
NHS Dictionary of Medicines and Devices	http://www.dmd.nhs.uk/
RFC 2119 - Key words for use in RFCs to Indicate Requirement Levels	http://www.faqs.org/rfcs/rfc2119.html

B Appendix 2 – Template Description

A brief description from the NHS Connecting for Health perspective.

1. A message template is a RMIM model that can be used to constrain another RMIM model in some way
2. In HL7 any model can be a template, no matter which classes it uses. This is because all classes can use the attribute “templateId” to identify the template
3. In the NHS CFH implementation, all classes can be templates with the exception of entities
4. The reason why the NHS CFH implementation does not support entity templating is related to NHS CFH’s use of two attributes (instead of using one attribute) in its templating mechanism i.e. the standard attribute “templateId” and the local attribute “contentId”
5. The local attribute “contentId” can only be present in the participation or “actRelationship” immediately prior to the template. Entities are not entered as a participation or “actRelationship” but via a playing or scoping association and therefore the use of this attribute is not possible when templating entities. NHS CFH has mandated the use of both attributes in its implementation and has accepted this causes a limitation
6. This limitation was deemed to have only minimal impact during the development of the templating mechanism and to the decision to use “contentId”
7. The RMIM has the artefact id format of “COCD_TPnnnnnnUKnn” to identify it as a message template
8. The model is saved to mif and html files in the MIM just like any other model
9. The directory / file structure in the MIM is a similar format to CMETs (Domains\Templates\ etc).

Example template



Where a template appears within a message or document model, a choice box with an abstract template class is used. The template class name, although abstract, must be unique within a model and therefore the template name may contain a number. This number is for uniqueness only and has no other significance.

Examples of abstract template classes

The structural attributes “classCode” and “moodCode” where shown in an abstract template class (circled below), are only shown due to a tooling limitation and have no relevance. These elements can be ignored by deployed systems, as this is a visual issue in the RMIM html diagram only and is not applicable to Tabular view schema or any other MIM artefact.