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SNOMED CT Implementation Guide for Allergy, Hypersensitivity and Intolerance

1.0

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Table of Contents

The SNOMED CT Implementation Guide for Allergy, Hypersensitivity, and Intolerance offers comprehensive guidance for healthcare providers, information managers, and software developers to standardize documenting adverse sensitivity data, including allergies, non-allergic hypersensitivity, and intolerance. It includes five chapters that introduce the guide, provide key use cases, elaborate on SNOMED CT terminological needs, introduce HL7 FHIR for data exchange, and present technical considerations for joint implementation. This guide is beneficial for healthcare providers, information managers, and software developers interested in integrating SNOMED CT into workflows within the domain of allergy, hypersensitivity, and intolerance.

Web browsable version: http://snomed.org/allergy

SNOMED CT Document Library: http://snomed.org/doc

Implementation demonstration: https://ihtsdo.github.io/sct-implementation-demonstrator/#/allergies

Executive Summary

This **SNOMED CT Implementation Guide for Allergy, Hypersensitivity, and Intolerance** provides comprehensive guidance for healthcare providers, information managers, and software developers who are seeking a standardized approach to document adverse sensitivity data (which encompasses allergy, non-allergic hypersensitivity and intolerance). The guide is designed to address the need for clear and uniform best practices for documenting adverse sensitivity and understanding how SNOMED CT can be applied within this domain.

The guide is organized into five main chapters, beginning with an introduction that outlines the objectives, scope, and target audience. The second chapter focuses on the key use cases that motivated the creation of this guide, providing clinical scenarios where SNOMED CT implementation is beneficial within the domain of allergy, hypersensitivity, and intolerance.
Chapter three elaborates on how SNOMED CT addresses the terminological needs within this domain, including relevant editorial policies and concept model rules established to ensure the quality of the content. Chapter four introduces HL7 FHIR as a recommended data exchange format/structure to facilitate the harmonization and interoperability of data within this domain. It also clarifies the bindings between HL7 FHIR AllergyIntolerance resouce elements and value sets and SNOMED CT. Finally, chapter five presents technical considerations related to the joint implementation of SNOMED CT and FHIR for allergy-related data capture, including two main ways to document adverse sensitivity in the EHR, which are supported by SNOMED CT: substance-focused and findings-focused models.

Overall, this SNOMED CT Implementation Guide provides practical guidance for healthcare providers, information managers, and software developers looking to integrate SNOMED CT into their workflows within the domain of allergy, hypersensitivity, and intolerance. It represents a culmination of work started by the Implementation SIG in 2014 and continued by the SNOMED International Clinical Reference Group for Allergies/Hypersensitivity starting in 2020.

The guide is particularly relevant for clinicians who are interested in understanding how SNOMED CT can support the needs for clinical documentation, clinical decision support and data sharing in the domain of allergy, hypersensitivity, and intolerance. It is also useful for information managers to learn how SNOMED CT can be integrated into health information models within this domain. Finally, software developers can learn how to integrate SNOMED CT into software applications in this domain and to exchange clinical data using HL7 FHIR.

1. Introduction

Background

The capture and exchange of adverse sensitivity data (which encompasses allergy, non-allergic hypersensitivity and intolerance) vary across EHRs. As an effect, much of this data is not interoperable across electronic systems. Confusion regarding the representation and definition of adverse sensitivity data within the EHR presents challenges to organizations that are trying to implement SNOMED CT for electronic data sharing. Further, this uncertainty limits the use of adverse sensitivity data for clinical decision support and longitudinal patient care records. The capture of allergy data must be clearly defined to support patient safety and a comprehensive health record.

Several Standards Development Organizations (SDOs), such as HL7, have provided some general guidance to assist implementers, however specific guidance in using SNOMED CT within this domain is lacking.

Objective

The overall objective of this guide is to promote interoperability within and between realms in a consistent way by providing clear guidance for structuring adverse sensitivity data as part of a patient's Electronic Health Record.

In addition, the objective is to enable consistent adoption of SNOMED CT within the domain of adverse sensitivity data by providing guidance on the representation of relevant information with different levels of granularity, with and without the use of post-coordination.

Scope

The scope of the work presented in this guide includes:

1. Review definitions and reference standards
2. Analyze relevant information models
    a. Review existing information models that are in scope, with special emphasis on HL7® FHIR® that has gained considerable momentum in recent years
3. Create exemplar use cases
    a. Describe the most common and important scenarios for capturing or exchanging adverse sensitivity information
    b. Illustrate how the information can be represented by using FHIR® and SNOMED CT concepts
4. Identify SNOMED CT subset
    a. Identify starter sets for large domains – most commonly used SNOMED CT concepts in clinical settings
    b. Identify value sets for specific data elements e.g., adverse sensitivity types, certainty, criticality, severity
5. Provide practical guidance on the use of SNOMED CT in
    a. Allergy list
    b. Problem list
    c. Clinical decision support

Audience

SNOMED CT is a comprehensive, multilingual clinical terminology that can be used to standardize and improve the quality of data related to allergies, hypersensitivities, and intolerances. This guide is targeted at the various stakeholders involved with the implementation of SNOMED CT:

- **SNOMED International Members** who are seeking uniform, clear best practices for documenting adverse sensitivity, and understanding how SNOMED CT can be applied in this domain
- **Clinicians** who are interested in understanding how SNOMED CT can support the clinical needs for data collection and acquisition within the field of Allergy, Hypersensitivity, and Intolerance.

- **Information managers** who are looking to learn how SNOMED CT can be integrated into health information models within the domain of Allergy, Hypersensitivity, and Intolerance to support the implementation of SNOMED CT and enhance data interoperability.
- **Software developers** who want to learn how to integrate SNOMED CT into software applications used in the domain of Allergy, Hypersensitivity, and Intolerance.

Attribution

This SNOMED CT Implementation guide and the underlying work have been developed by the SNOMED International Clinical Reference Group for Allergies/Hypersensitivity. The Clinical Reference Group (CRG) is composed of experts in the field of Allergies/Hypersensitivity providing input from the community of practice on the development, maintenance, and use of SNOMED CT in this specific domain. The CRG members have been instrumental in the development of this guide, providing their expertise, knowledge, and experience to ensure that it is accurate, up-to-date, and relevant to the needs of its intended audience. Their dedication and hard work have made this guide possible and SNOMED Internationalis is grateful for their contributions. This guide is a product of SNOMED International's ongoing commitment to improving healthcare through the use of high-quality, standardized clinical terminologies.

Guide Overview

This SNOMED CT Implementation Guide is designed to provide guidance for the use of SNOMED CT within the domain of allergies, hypersensitivity, and intolerance. The guide is organized into five main chapters:

- Chapter 1: **Introduction** - This chapter provides a background on the guide, including the objectives, scope, and target audience.
- Chapter 2: **Clinical Use Cases** - This chapter describes the key use cases that have motivated the creation of this guide and explains scenarios where implementation of SNOMED CT within this domain is needed.
- Chapter 3: **Allergy Content in SNOMED CT** - This chapter describes how SNOMED CT addresses the terminological needs within the domain of allergies, hypersensitivities, and intolerances. It also elaborates on relevant editorial policies and concept model rules established to ensure the quality of the content.
- Chapter 4: **Information Model and Terminology Binding** - This chapter introduces HL7 FHIR as a recommended information model that can be used within the field of allergies, hypersensitivities, and intolerances to facilitate the harmonization and interoperability of data within this domain. It also clarifies the bindings between this and SNOMED CT.
- Chapter 5: **Technical Application** - This chapter presents technical considerations related the implementation of SNOMED CT and FHIR for allergy-related data capture.

In addition, a number of appendixes present the results of the analysis performed and provide insights into the evolution of SNOMED CT and available information models.

- Appendix A: Glossary of Terms
- Appendix B: Historical SNOMED CT content perspective
- Appendix C: Analysis of the HL7 C-CDA model
- Appendix D: Analysis of the HL7 Patient Care Domain Analysis Model
- Appendix E: Analysis of the ISO International Patient Summary (IPS)
- Appendix F: Analysis of the epSOS information model
- Appendix G: Analysis of the openEHR information model
- Appendix H: Analysis of the US Federal Health Information Model
- Appendix I: Inclusive Information Model

Review

This SNOMED CT Implementation guide represents the culmination of work started by the Implementation SIG in 2014 and and continued by the SNOMED International Clinical Reference Group for Allergies/Hypersensitivity starting in 2020.

We welcome feedback from readers on the guide and encourage them to share their insights and experiences with us. Your comments and suggestions will help us improve the content of the guide and ensure that it is relevant and useful to those who use it. We will review any feedback received and make updates to the guide as needed.

We appreciate your interest in this guide and thank you for your contributions to the improvement of healthcare through the use of high-quality, standardized clinical terminologies like SNOMED CT. Please raise any comments to this document via the feedback button (At the bottom of the page).

2. Clinical Use Case

Allergic, hypersensitive, and intolerant reactions can be avoided by preventing the prescription and administration of, or exposure to known trigger substances. The proper documentation of known allergic, hypersensitivity, or intolerance episodes is critical to making this knowledge available at the point of care and supporting decision-making that would prevent future situations. Information needs to be recorded with the right level of detail and context to support these processes.

This page summarizes the key use cases covered by this guide. See section 4.3 for detailed examples.

Use Case 1: Documentation of Information Related to Allergy, Hypersensitivity, and Intolerance

Scenario 1.1: Documentation of an adverse reaction to a drug substance

Healthcare providers should be able to accurately record the details of a patient's adverse reaction to a drug substance. This information includes the drug substance involved, routes of administration, dosage, signs, and symptoms produced by the reaction, time frames, etc., allowing for clear and consistent documentation and communication between healthcare providers. This can improve patient care by facilitating a more accurate understanding of the reaction and facilitating the identification of potential risk factors. Additionally, the use of SNOMED CT can support research and data analysis on adverse drug reactions.

Scenario 1.2: Documentation of drug allergy in the allergy list and use as alert to provider

SNOMED CT can be used to document drug allergies in the allergy list and serve as an alert trigger to providers. This will allow providers to quickly and accurately identify drugs that a patient may be allergic to, for instance as they prescribe. SNOMED CT is used to identify potential allergy triggers in the patient's medical history and assist providers in determining the safest and most effective treatment options for the patient.

Scenario 1.3: Documentation of a food intolerance

Healthcare providers should be able to record the details of a patient's food intolerance accurately. This information includes the type of food, examination results, signs, and symptoms produced by the intolerance, time frames, etc., allowing for clear and consistent documentation and communication between healthcare providers. This can improve patient care by facilitating a more accurate understanding of intolerance events and facilitating the identification of potential risk factors. Additionally, the use of SNOMED CT can support research and data analysis on food intolerance, food allergies and cross reactivities.

Scenario 1.4: Documentation of animal allergy

Healthcare providers should be able to record the details of a patient's animal accurately. This information includes the type of animal, exposure, examination results, signs and symptoms produced by the allergy, time frames, etc., allowing for clear and consistent documentation and communication between healthcare providers. This can improve patient care by facilitating a more accurate understanding of his/her environmental allergic events and facilitating the identification of potential risk factors /situations. Additionally, the use of SNOMED CT can support research and data analysis on animal allergy.

Scenario 1.5: Documentation of allergy to non-medicinal substance cross-reacting with a pharmaceutical

SNOMED CT can be used to document non-medicinal substance allergies in the allergy list, which can cross-react with ingredients of medications or be an excipient in medications and thus serve as an alert to providers when prescribing a drug treatment. This will allow providers to quickly and accurately identify drug classes or

specific branded drugs or drug forms a patient may be allergic to based on previously recorded allergies to non-medicinal ingredients. SNOMED CT is used to identify potential allergy triggers in the patient's medical history and assist providers in determining the safest and most effective treatment options for the patient.

Scenario 1.6: Documentation of allergic reaction to other non-medicinal substances

Healthcare providers should be able to record allergic reactions to other non-medicinal substances accurately. This information includes the type of non-medicinal substance, examination results, signs, and symptoms produced by the reaction, time frames, etc., allowing for clear and consistent documentation and communication between healthcare providers. This can improve patient care and general life by facilitating a more accurate understanding of allergic reactions and facilitating the identification of potential risk factors, situations or products to avoid in everyday life or protection equipment needed during professional exposure. Additionally, the use of SNOMED CT can support research and data analysis on allergic reactions.

Scenario 1.7: Documentation of 'No Known Allergies'

Healthcare providers should be able to record when a patient reports that he/she has no allergy history, with the data and time of the report.

Use Case 2: Sharing of Information Related to Allergy, Hypersensitivity, and Intolerance

Scenario 2.1: Sharing adverse reaction data

Electronically-stored allergy, hypersensitivity and intolerance information information should be semantically interoperable to enable sharing of information across system, organization and geographic boundaries.

Use Case 3: Supporting the Implementation of Decision Support Systems

Scenario 3.1: Potential adverse reaction alerts

Electronic health records should be able to leverage the stored information to run clinical decision support systems to alert clinicians of potential adverse reactions due to allergy, hypersensitivity and intolerance.

3. Allergy Content in SNOMED CT

SNOMED CT concept model

The SNOMED CT concept model for allergy-related conditions has undergone significant changes (see Appendix B: Historical SNOMED CT content perspective for the history of changes). Currently, SNOMED allergy content is organized under the umbrella of hypersensitivity, which is defined by the World Allergy Organization (WAO) as "objectively reproducible symptoms or signs initiated by exposure to a defined stimulus at a dose tolerated by normal persons".

Hypersensitivity encompasses both allergy and non-allergic hypersensitivity. The top-level organizing nodes representing hypersensitivity, allergy, and non-allergic hypersensitivity are referred to as conditions (representing disease states), dispositions (propensities to develop a reaction), and processes (pathological processes underlying the reactions). The disjunctive nature of these conditions is modeled using general concept inclusions (GCIs). Hypersensitivity conditions, including allergy and non-allergic hypersensitivity, are defined in terms of a pathologic process relationship to specific processes in the qualifier value hierarchy.

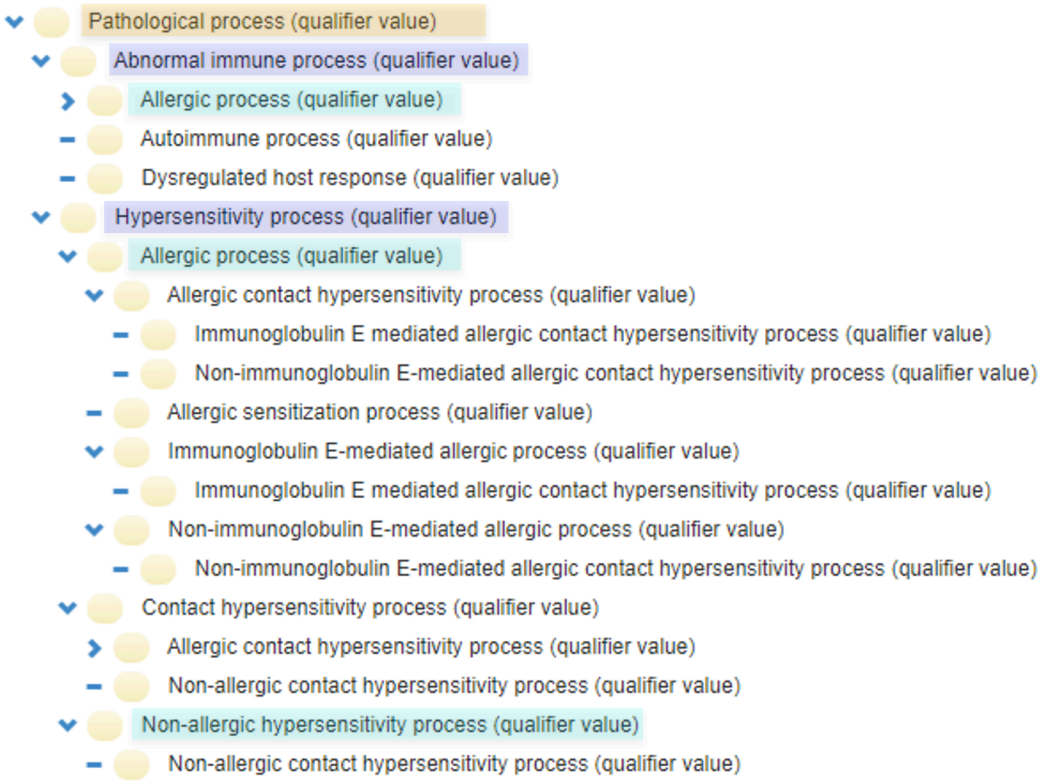

Figure 3-1: Hierarchical view of the hypersensitivity pathological processes as available in SNOMED CT International Edition version 20220831.

Allergic Conditions

Allergic conditions are defined as kinds of hypersensitivity diseases, propensities, and reactions with an immunologic basis and are modeled with a pathologic process of the Allergic process (qualifier value) hierarchy. Allergic process (qualifier value) is a child of both the Hypersensitivity process (qualifier value) and Abnormal immune process (qualifier value), and thus allergic diseases and reactions, unlike their non-allergic counterparts, will classify under both Hypersensitivity condition (finding) and Disorder of immune function.

Various contact hypersensitivity processes, such as allergic (IgE and non-IgE mediated) and non-allergic, are used to model allergic contact urticaria, allergic contact dermatitis, and irritant contact dermatitis, respectively.

Concept models for representative allergic conditions are illustrated below (in the stated view). A similar approach is used to model unspecified hypersensitivity and non-allergic hypersensitivity diseases, propensities, and reactions.

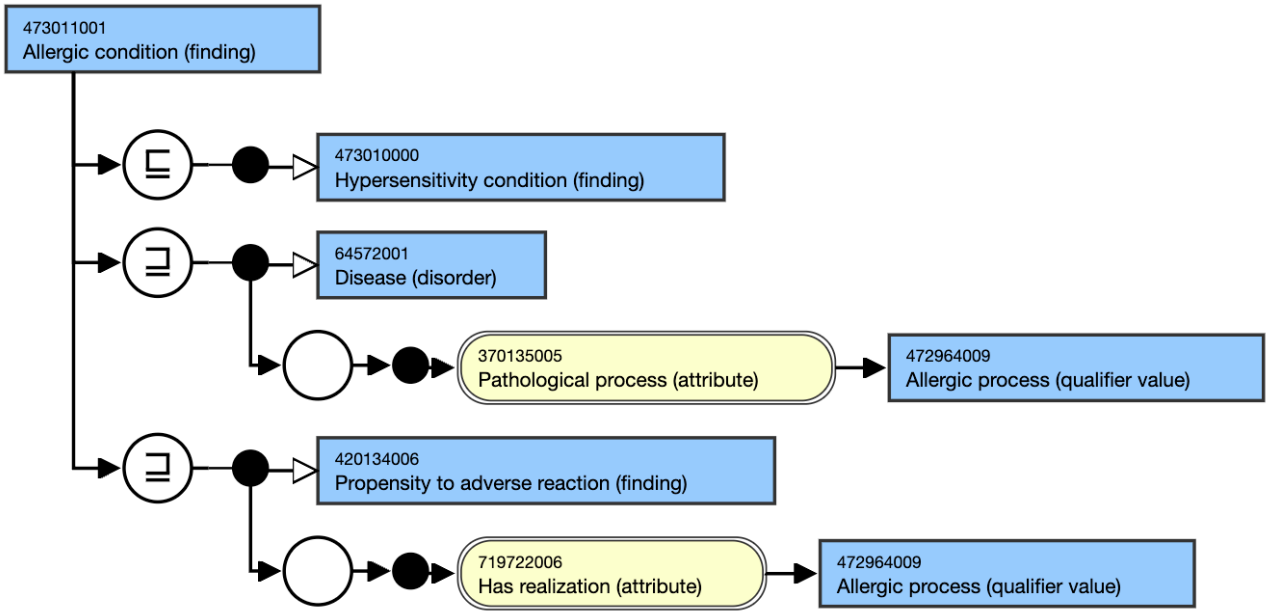

Figure 3-2: Diagrammatic representation in stated view of concept 473011001 |Allergic condition (finding)|as in the International Edition version 20220831.

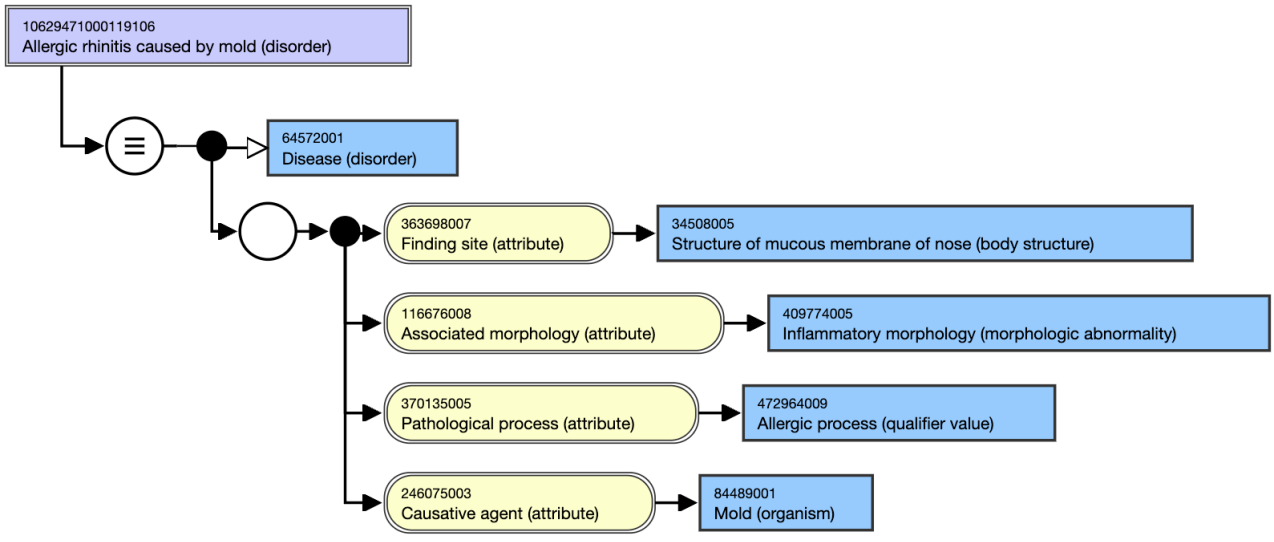

Figure 3-3: Diagrammatic representation in stated view of concept 10629471000119106 | Allergic rhinitis caused by mold (disorder)| as in the International Edition version 20220831.

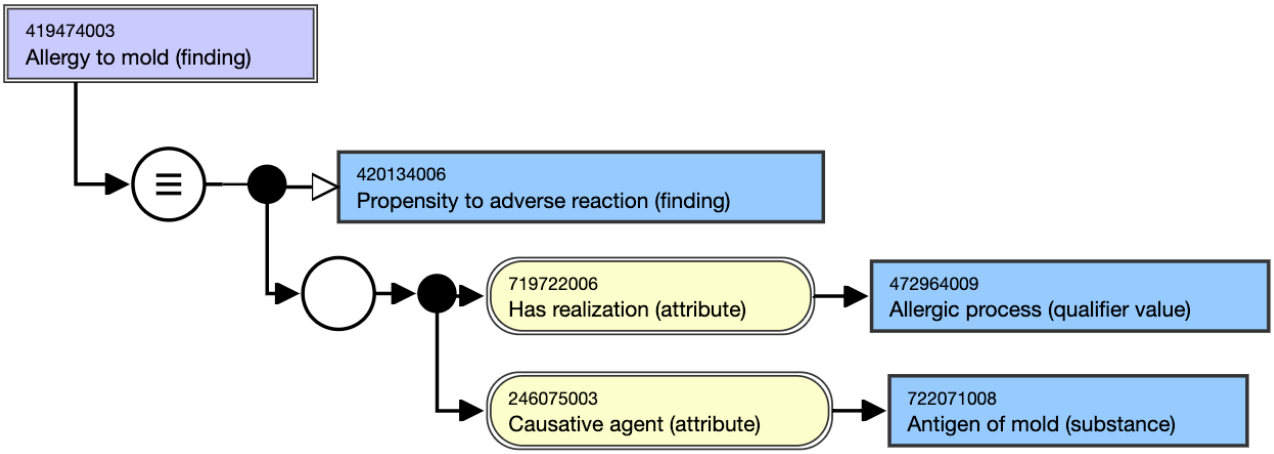

Figure 3-4: Diagrammatic representation in stated view of concept 419474003 |Allergy to mold (finding)| as in the International Edition version 20220831.

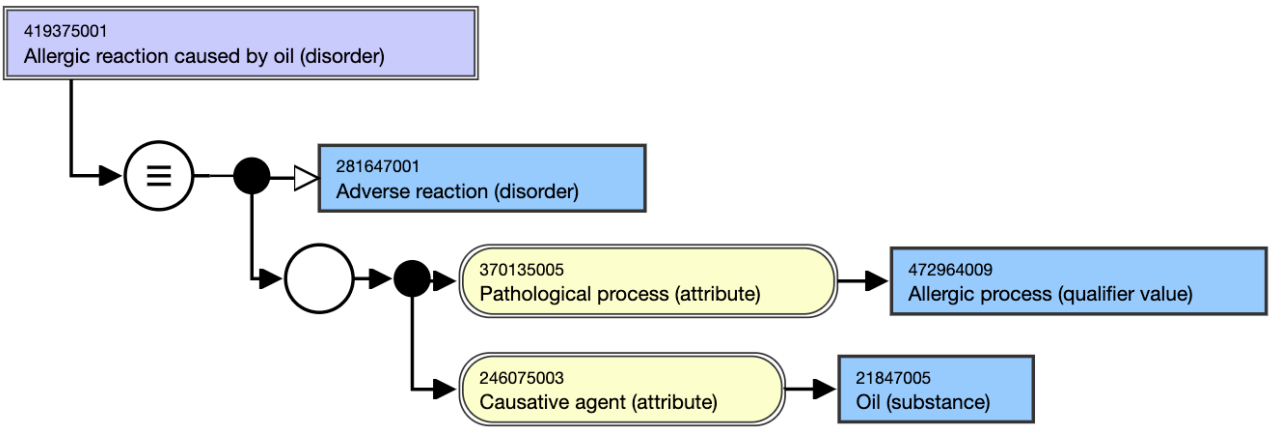

Figure 3-5: Diagrammatic representation in stated view of concept 419375001 |Allergic reaction caused by oil (disorder)|as in the International Edition version 20220831.

Intolerance

Intolerance (to a substance) is a propensity to an adverse reaction, which is not an allergy or a non-allergic hypersensitivity, and may be idiosyncratic and/or individually specific (as noted in FHIR® Release 4). 782197009 | Intolerance to substance (finding)| is thus a sibling to 609433001 | Hypersensitivity disposition (finding)| and is modeled as shown below:

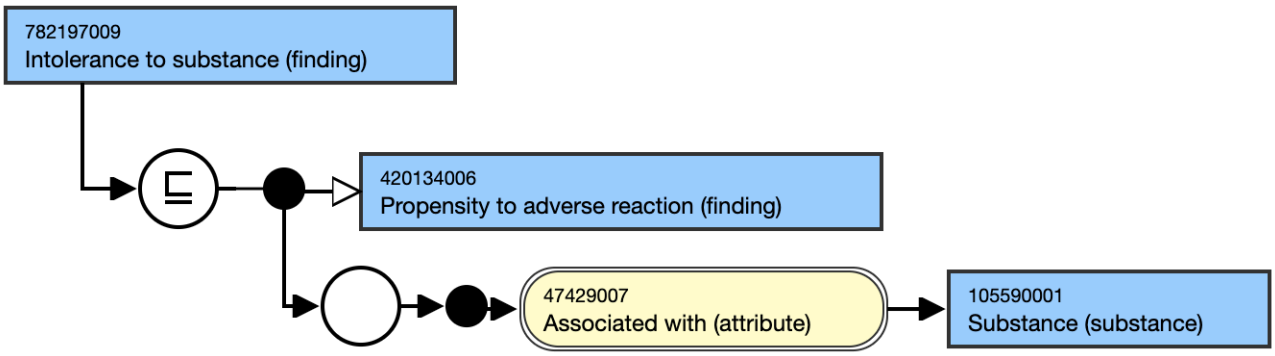

Figure 3-6: Diagrammatic representation in stated view of concept 782197009 |Intolerance to substance (finding)|as in the International Edition version 20230228

4. Information Model and Terminology Binding

The use of SNOMED CT for recording Allergy, Hypersensitivity, and Intolerance requires the definition of an information model and terminology bindings. This will ensure that the information is captured in a consistent and standardized way, which can be used to facilitate better communication and decision-making between healthcare providers. Furthermore, it will enable the sharing of health information between different systems and facilitate better analysis of health data. By defining an information model and terminology bindings, healthcare organizations can ensure that their data is accurately recorded and can be used in a meaningful way.

The use of HL7® FHIR® with SNOMED CT has gained considerable momentum in recent years, and HL7 FHIR has therefore been selected as the preferred information model in this guide. The following pages will discuss recommended approaches for binding SNOMED to HL7 FHIR for documenting Allergies, Hypersensitivity, and Intolerance in the EHR.

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4.1 FHIR model

FHIR® is an HL7® standard for exchanging healthcare information electronically. The fourth STU release (R4) was published in October 2019, including the first (partial) normative content. FHIR models the classes of information for interoperable use as Resources. The FHIR® Resources relevant to the use cases in section 4 are AllergyIntolerance, Condition and Observation.

AllergyIntolerance resource

Figure 4.1-1 shows the structure of the FHIR AllergyIntolerance resource. The full resource model structure, coded elements and terminology bindings of the AllergyIntolerance resource can be found at http://www.hl7.org/fhir/allergyintolerance.html, with various display options, including UML, XML, JSON, Turtle and the differences it underwent compared to the prior release(s).

Structure

Name	Flags	Card.	Type	Description & Constraints
AllergyIntolerance	TU		DomainResource	Allergy or Intolerance (generally: Risk of adverse reaction to a substance) Elements defined in Ancestors: id, meta, implicitRules, language, text, contained, extension, modifierExtension
identifier	Σ	0..*	Identifier	External ids for this item
clinicalStatus	?! Σ	0..1	CodeableConcept	active | inactive | resolved Binding: AllergyIntolerance Clinical Status Codes (Required)
verificationStatus	?! Σ	0..1	CodeableConcept	unconfirmed | presumed | confirmed | refuted | entered-in-error Binding: AllergyIntolerance Verification Status (Required)
type	Σ TU	0..1	CodeableConcept	allergy | intolerance - Underlying mechanism (if known) Binding: Allergy Intolerance Type (Preferred)
category	Σ	0..*	code	food | medication | environment | biologic Binding: Allergy Intolerance Category (Required)
criticality	Σ	0..1	code	low | high | unable-to-assess Binding: Allergy Intolerance Criticality (Required)
code	Σ	0..1	CodeableConcept	Code that identifies the allergy or intolerance Binding: AllergyIntolerance Substance/Product, Condition and Negation Codes (Example)
patient	Σ	1..1	Reference(Patient)	Who the allergy or intolerance is for
encounter		0..1	Reference(Encounter)	Encounter when the allergy or intolerance was asserted
onset[x]		0..1		When allergy or intolerance was identified
onsetDateTime			dateTime	
onsetAge			Age	
onsetPeriod			Period	
onsetRange			Range	
onsetString			string	
recordedDate		0..1	dateTime	Date allergy or intolerance was first recorded
participant	Σ	0..*	BackboneElement	Who or what participated in the activities related to the allergy or intolerance and how they were involved
function	Σ	0..1	CodeableConcept	Type of involvement Binding: Participation Role Type (Extensible)
actor	Σ	1..1	Reference(Practitioner | PractitionerRole | Patient | RelatedPerson | Device | Organization | CareTeam)	Who or what participated in the activities related to the allergy or intolerance
lastOccurrence		0..1	dateTime	Date(/time) of last known occurrence of a reaction
note		0..*	Annotation	Additional text not captured in other fields
reaction	TU	0..*	BackboneElement	Adverse Reaction Events linked to exposure to substance
substance		0..1	CodeableConcept	Specific substance or pharmaceutical product considered to be responsible for event Binding: Substance Code (Example)
manifestation		1..*	CodeableReference(Observation)	Clinical symptoms/signs associated with the Event Binding: SNOMED CT Clinical Findings (Example)
description		0..1	string	Description of the event as a whole
onset		0..1	dateTime	Date(/time) when manifestations showed
severity		0..1	code	mild | moderate | severe (of event as a whole) Binding: Allergy Intolerance Severity (Required)
exposureRoute		0..1	CodeableConcept	How the subject was exposed to the substance Binding: SNOMED CT Route Codes (Example)
note		0..*	Annotation	Text about event not captured in other fields

Figure 4.1-1: Structure of the AllergyIntolerance HL7 FHIR resource as in HL7® FHIR® v4.3.0: R4B - STU (From http://www.hl7.org/fhir/allergyintolerance.html, consulted on 2nd September 2022).

The scope of this resource is to "Record of a clinical assessment of an allergy or intolerance; a propensity, or a potential risk to an individual, to have an adverse reaction on future exposure to the specified substance, or class of substance.

Where a propensity is identified, to record information or evidence about a reaction event that is characterized by any harmful or undesirable physiological response that is specific to the individual and triggered by exposure of an individual to the identified substance or class of substance.

Substances include, but are not limited to: a therapeutic substance administered correctly at an appropriate dosage for the individual; food; material derived from plants or animals; or venom from insect stings."

Table 4.1-1: The definition of the main AllergyIntolerance resource elements along with details about their terminology bindings.

Path/Element	Definition	Values	Binding Strength	Binding
AllergyIntolerance .clinicalStatus	The clinical status of the allergy or intolerance.	- active - inactive - resolved	Required	AllergyIntoleranceClinicalStatusCodes
AllergyIntolerance .verificationStatus	Assertion about certainty associated with a propensity, or potential risk, of a reaction to the identified substance.	- unconfirmed - confirmed - refuted - entered-in-error	Required	AllergyIntoleranceVerificationStatusCodes
AllergyIntolerance.type	Identification of the underlying physiological mechanism for the reaction risk, if known.	- allergy - intolerance	Required	AllergyIntoleranceType
AllergyIntolerance .category	Category of an identified substance associated with allergies or intolerances.	- food - medication - environment - biologic	Required	AllergyIntoleranceCategory
AllergyIntolerance .criticality	Estimate of the potential clinical harm, or seriousness, of a reaction to an identified substance.	- low - high - unable-to-assess	Required	AllergyIntoleranceCriticality
AllergyIntolerance.code	Code for an allergy or intolerance statement (either a positive or a negated/excluded statement). This may be a code for a substance or pharmaceutical product that is considered to be responsible for the adverse reaction risk (e.g., "Latex"), an allergy or intolerance condition (e.g., "Latex allergy"), or a negated/excluded code for a specific substance or class (e.g., "No latex allergy") or a general or categorical negated statement (e.g., "No known allergy", "No known drug allergies").		Example	AllergyIntoleranceSubstance / Product,ConditionAndNegationCodes
AllergyIntolerance .reaction.substance	Identification of the specific substance (or pharmaceutical product) considered to be responsible for the Adverse Reaction manifestation. It can differ from the AllergyIntolerance.code in some circumstances (ex: reaction to a product containing the substance responsible).		Example	SubstanceCode
AllergyIntolerance .reaction.manifestation	Clinical symptoms and/or signs that are observed or associated with an Adverse Reaction Event.		Example	SNOMEDCTClinicalFindings
AllergyIntolerance .reaction.severity	Clinical assessment of the severity of a reaction event *as a whole*, potentially	- mild - moderate - severe	Required	AllergyIntoleranceSeverity

Path/Element	Definition	Values	Binding Strength	Binding
	considering multiple different manifestations.			
AllergyIntolerance .reaction.exposureRoute	A coded concept describing the route or physiological path by which the subject was exposed to the substance.		Example	SNOMEDCTRouteCodes

It is important to note that

- In the FHIR® AllergyIntolerance resource, some elements (type, category, criticality and severity) have currently a "Code" data type. They thus require the use of the FHIR values provided and no other classification or terminology code can be used as value in these elements, unless one is using a FHIR® extension, while other elements (clinicalStatus, verificationStatus) have a "CodeableConcept" data type and thus allow for simultaneous use of several code systems (ex: both the FHIR values and the SNOMED CT concepts representing the same meaning as those FHIR values).

Here you will find an example of extension for AllergyIntolerance.type, which allows capturing, in SNOMED CT, more type of reaction values then the two FHIR values of "allergy" and "intolerance". The full discussion regarding this extension can be found on the 22/02/2022 SNOMED on FHIR group meeting page.

- When FHIR® R5 is released (expected in late 2022):
  - The reaction.manifestation element should be able to directly reference a FHIR Observation resource representing the manifestation (proposal to be balloted in R5). This will allow the manifestation of an adverse reaction to be recorded only once, not first in an Observation resource and then once again in the AllergyIntolerance resource.
  - The AllergyIntolerance.type element will have a "CodeableConcept" data type and a binding strength of "Preferred", thus allowing the use of SNOMED CT concepts as values without the use of an extension.

Observation resource

Figure 4.1-2 shows the structure of the FHIR Observation resource. The full resource model structure, coded elements and terminology bindings of the Observation resource can be found on http://www.hl7.org/fhir/observation.html, with various display options, including UML, XML, JSON, Turtle and the differences it underwent compared to the prior release(s).

Structure

Name	Flags	Card.	Type	Description & Constraints
Observation	N		DomainResource	Measurements and simple assertions + *Rule: dataAbsentReason SHALL only be present if Observation.value[x] is not present* + *Rule: If Observation.component.code is the same as Observation.code, then Observation.value SHALL NOT be present (the Observation.component.value[x] holds the value).* + *Rule: bodyStructure SHALL only be present if Observation.bodySite is not present* Elements defined in Ancestors: id, meta, implicitRules, language, text, contained, extension, modifierExtension
identifier	Σ	0..*	Identifier	Business Identifier for observation
instantiates[x]	Σ TU	0..1		Instantiates FHIR ObservationDefinition
basedOn	Σ	0..*	Reference(CarePlan | DeviceRequest | ImmunizationRecommendation | MedicationRequest | NutritionOrder | ServiceRequest)	Fulfills plan, proposal or order
triggeredBy	TU	0..*	BackboneElement	Triggering observation(s)
observation	Σ	1..1	Reference(Observation)	Triggering observation
type	Σ	1..1	code	reflex | repeat | re-run Binding: triggered Bytype (Required)
reason		0..1	string	Reason that the observation was triggered
partOf	Σ	0..*	Reference(MedicationAdministration | MedicationDispense | MedicationStatement | Procedure | Immunization | ImagingStudy | GenomicStudy)	Part of referenced event
status	?! Σ	1..1	code	registered | preliminary | final | amended + Binding: Observation Status (Required)
category		0..*	CodeableConcept	Classification of type of observation Binding: Observation Category Codes (Preferred)
code	Σ C	1..1	CodeableConcept	Type of observation (code / type) Binding: LOINC Codes (Example)
subject	Σ	0..1	Reference(Patient | Group | Device | Location | Organization | Procedure | Practitioner | Medication | Substance | BiologicallyDerivedProduct | NutritionProduct)	Who and/or what the observation is about
focus	Σ TU	0..*	Reference(Any)	What the observation is about, when it is not about the subject of record
encounter	Σ	0..1	Reference(Encounter)	Healthcare event during which this observation is made
effective[x]	Σ	0..1		Clinically relevant time/time-period for observation
issued	Σ	0..1	instant	Date/Time this version was made available
performer	Σ	0..*	Reference(Practitioner | PractitionerRole | Organization | CareTeam | Patient | RelatedPerson)	Who is responsible for the observation
value[x]	Σ C	0..1		Actual result
dataAbsentReason	C	0..1	CodeableConcept	Why the result is missing Binding: Data Absent Reason (Extensible)
interpretation		0..*	CodeableConcept	High, low, normal, etc Binding: Observation Interpretation Codes (Extensible)
note		0..*	Annotation	Comments about the observation
bodySite	C	0..1	CodeableConcept	Observed body part Binding: SNOMED CT Body Structures (Example)
bodyStructure	C TU	0..1	Reference(BodyStructure)	Observed body structure
method		0..1	CodeableConcept	How it was done Binding: Observation Methods (Example)
specimen	C	0..1	Reference(Specimen | Group)	Specimen used for this observation + *Rule: If Observation.specimen is a reference to Group, the group can only have specimens*
device		0..1	Reference(Device | DeviceMetric)	A reference to the device that generates the measurements or the device settings for the device
referenceRange	C	0..*	BackboneElement	Provides guide for interpretation + *Rule: Must have at least a low or a high or text*
low	C	0..1	SimpleQuantity	Low Range, if relevant
high	C	0..1	SimpleQuantity	High Range, if relevant
normalValue	TU	0..1	CodeableConcept	Normal value, if relevant Binding: Observation Reference Range Normal Value Codes (Extensible)
type	TU	0..1	CodeableConcept	Reference range qualifier Binding: Observation Reference Range Meaning Codes (Preferred)
appliesTo		0..*	CodeableConcept	Reference range population Binding: Observation Reference Range Applies To Codes (Example)
age		0..1	Range	Applicable age range, if relevant
text	C	0..1	markdown	Text based reference range in an observation
hasMember	Σ	0..*	Reference(Observation | QuestionnaireResponse | MolecularSequence)	Related resource that belongs to the Observation group
derivedFrom	Σ	0..*	Reference(DocumentReference | ImagingStudy | ImagingSelection | QuestionnaireResponse | Observation | MolecularSequence | GenomicStudy)	Related resource from which the observation is made
component	Σ C	0..*	BackboneElement	Component results

Figure 4.1-2: Structure of the Observation HL7 FHIR resource as in HL7® FHIR® v4.3.0: R4B - STU (From http://www.hl7.org/fhir/observation.html, consulted on 2nd September 2022).

Observations in general are a central element in healthcare, used to support diagnosis, monitor progress, determine baselines and patterns and even capture demographic characteristics. Most observations are simple name/value pair assertions with some metadata, but some observations group other observations together logically, or even are multi-component observations. Note that the DiagnosticReport resource provides a clinical or workflow context for a set of observations and the Observation resource is referenced by DiagnosticReport to represent laboratory, imaging, and other clinical and diagnostic data to form a complete report. In the context of allergies, it can be used to present allergy test results.

Uses for the Observation resource include:

- Vital signs such as body weight, blood pressure, and temperature
- **Laboratory Data** like blood glucose, or an estimated GFR
- Imaging results like bone density or fetal measurements
- **Clinical Findings** such as abdominal tenderness
- Device measurements such as EKG data or Pulse Oximetry data
- Clinical assessment tools such as APGAR or a Glasgow Coma Score
- Personal characteristics: such as eye-color
- Social history like tobacco use, family support, or cognitive status
- Core characteristics like pregnancy status, or a death assertion

In the context of allergies, the Observation resource can be used to record the manifestation(s) of the allergy (ex: rash on the neck). Note that the boundary between observing a (series of) clinical finding(s) and posing the diagnosis of a disorder isn't always clear cut in medical ontology, and explicit local business rules may be needed to help clinicians record the same clinical situations either as observations or as diagnosis in a consistent way. The Observation resource can also be used to record allergy test results (biological test, like dosage of specific IgE or clinical, like patch and prick tests).

Table 4.1-2: The definition of the main Observation resource elements along with details about their terminology bindings.

Path/Element	Definition	Values	Binding Strength	Binding
Observation.status	The status of the result value.	- registered - preliminary - final - amended - corrected - cancelled - entered in error - unknown	Required	ObservationStatus
Observation.category	A code that classifies the general type of observation being made.		Preferred	Observation Category Codes
Observation.code	Type of observation (code / type). Describes what was observed. Sometimes this is called the observation "name".		Example	LOINC Codes

Observation.dataAbsentReason	Provides a reason why the expected value in the element Observation.value[x] is missing.		Extensible	DataAbsentReason
Observation.interpretation	A categorical assessment of an observation value. For example, high, low, normal.		Extensible	Observation InterpretationCodes
Observation.bodySite	Indicates the site on the subject's body where the observation was made (i.e. the target site). May include laterality.		Example	SNOMED CT Body Structures
Observation.method	Indicates the mechanism used to perform the observation.		Example	ObservationMethods
Observation.referenceRange.type	Codes to indicate the what part of the targeted reference population it applies to. For example, the normal or therapeutic range.		Preferred	Observation Reference Range MeaningCodes
Observation.referenceRange.appliesTo	Codes to indicate the target population this reference range applies to. For example, a reference range may be based on the normal population or a particular sex or race.		Example	Observation Reference Range AppliesToCodes
Observation.component.code	Type of component observation (code / type). Describes what was observed. Sometimes this is called the observation "code".		Example	LOINC Codes
Observation.component.dataAbsentreason	Provides a reason why the expected value in the element Observation.component.value[x] is missing.		Extensible	DataAbsentReason
Observation.component.interpretation	A categorical assessment of an observation value. For example, high, low, normal.		Extensible	Observation InterpretationCodes

Condition resource

Figure 4.1-3 shows the structure of the FHIR Condition resource. The resource model structure, coded elements and terminology bindings of the Condition resource can be found on http://www.hl7.org/fhir/condition.html, with various display options, including UML, XML, JSON, Turtle and the differences it underwent compared to the prior release(s).

Structure

Name	Flags	Card.	Type	Description & Constraints
Condition	TU		DomainResource	Detailed information about conditions, problems or diagnoses *+ Warning: If category is problems list item, the clinicalStatus should not be unknown* *+ Rule: If condition is abated, then clinicalStatus must be either inactive, resolved, or remission.* Elements defined in Ancestors: id, meta, implicitRules, language, text, contained, extension, modifierExtension
identifier	Σ	0..*	Identifier	External Ids for this condition
clinicalStatus	?! Σ C	1..1	CodeableConcept	active | recurrence | relapse | inactive | remission | resolved | unknown Binding: Condition Clinical Status Codes (Required)
verificationStatus	?! Σ	0..1	CodeableConcept	unconfirmed | provisional | differential | confirmed | refuted | entered-in-error Binding: Condition Verification Status (Required)
category	C	0..*	CodeableConcept	problem-list-item | encounter-diagnosis Binding: Condition Category Codes (Preferred)
severity		0..1	CodeableConcept	Subjective severity of condition Binding: Condition/Diagnosis Severity (Preferred)
code	Σ	0..1	CodeableConcept	Identification of the condition, problem or diagnosis Binding: Condition/Problem/Diagnosis Codes (Example)
bodySite	Σ	0..*	CodeableConcept	Anatomical location, if relevant Binding: SNOMED CT Body Structures (Example)
subject	Σ	1..1	Reference(Patient | Group)	Who has the condition?
encounter	Σ	0..1	Reference(Encounter)	The Encounter during which this Condition was created
onset[x]	Σ	0..1		Estimated or actual date, date-time, or age
onsetDateTime			dateTime	
onsetAge			Age	
onsetPeriod			Period	
onsetRange			Range	
onsetString			string	
abatement[x]	C	0..1		When in resolution/remission
abatementDateTime			dateTime	
abatementAge			Age	
abatementPeriod			Period	
abatementRange			Range	
abatementString			string	
recordedDate	Σ	0..1	dateTime	Date condition was first recorded
participant	Σ	0..*	BackboneElement	Who or what participated in the activities related to the condition and how they were involved
function	Σ	0..1	CodeableConcept	Type of involvement Binding: Participation Role Type (Extensible)
actor	Σ	1..1	Reference(Practitioner | PractitionerRole | Patient | RelatedPerson | Device | Organization | CareTeam)	Who or what participated in the activities related to the condition
stage	C TU	0..*	BackboneElement	Stage/grade, usually assessed formally *+ Rule: Stage SHALL have summary or assessment*
summary	C	0..1	CodeableConcept	Simple summary (disease specific) Binding: Condition Stage (Example)
assessment	C	0..*	Reference(ClinicalImpression | DiagnosticReport | Observation)	Formal record of assessment
type		0..1	CodeableConcept	Kind of staging Binding: Condition Stage Type (Example)
evidence	Σ TU	0..*	CodeableReference(Any)	Supporting evidence for the verification status Binding: SNOMED CT Clinical Findings (Example)
note		0..*	Annotation	Additional information about the Condition

Figure 4.1-3: Structure of the Condition HL7 FHIR resource as in HL7® FHIR® v4.3.0: R4B - STU (From http://www.hl7.org/fhir/condition.html, consulted on 2nd September 2022)

This resource is used to record detailed information about a condition, problem, diagnosis, or other event, situation, issue, or clinical concept that has risen to a level of concern. The condition could be a point in time diagnosis in the context of an encounter, it could be an item on the practitioner's Problem List, or it could be an additional concern that does not exist on the practitioner's Problem List. Often a condition is about a clinician's assessment and assertion of a particular aspect of a patient's state of health. It can be used to record information about a disease/illness identified from application of clinical reasoning over the pathologic and pathophysiologic findings (diagnosis), or identification of health issues/situations that a practitioner considers harmful or potentially harmful and may be investigated and managed (problem), or another health issue/situation that may require ongoing monitoring and/or management (health issue/concern).

While conditions are frequently a result of a clinician's assessment and assertion of a particular aspect of a patient's state of health, conditions can also be expressed by the patient, related person, or any care team member. A clinician may have a concern about a patient condition (e.g. anorexia) that the patient is not concerned about. Likewise, the patient may have a condition (e.g. hair loss) that does not rise to the level of importance such that it belongs on a practitioner's Problem List.

In the context of allergies, the Condition resource can be used to record the manifestation(s) of the allergy (ex: allergic urticaria).

Table 4.1-3: The definition of the main Condition resource elements along with details about their terminology bindings.

Path/Element	Definition	Values	Binding Strength	Binding
Condition.clinicalStatus	The clinical status of the condition or diagnosis.	- active - recurrence - relapse - inactive - remission - resolved	Required	ConditionClinicalStatusCodes
Condition.verificationStatus	The verification status to support or decline the clinical status of the condition or diagnosis.	- unconfirmed - provisional - differential - confirmed - refuted - entered-in-error	Required	ConditionVerificationStatus
Condition.category	A category assigned to the condition.		Extensible	ConditionCategoryCodes
Condition.severity	A subjective assessment of the severity of the condition as evaluated by the clinician.		Preferred	Condition/DiagnosisSeverity
Condition.code	Identification of the condition or diagnosis.		Example	Condition/Problem/DiagnosisCodes
Condition.bodySite	Codes describing anatomical locations. May include laterality.		Example	SNOMEDCTBodyStructures
Condition.stage.summary	Codes describing condition stages (e.g. Cancer stages).		Example	ConditionStage
Condition.stage.type	Codes describing the kind of condition staging (e.g. clinical or pathological).		Example	ConditionStageType
Condition.evidence.code	Codes that describe the manifestation or symptoms of a condition.		Example	ManifestationAndSymptomCodes

1.1.3.4 Example of a typical Medication allergy resource from a clinical system (id = "medication") (JSON format):


```
{
  "resourceType": "AllergyIntolerance",
  "id": "medication",
  "text": {
    "status": "generated",
    "div": "<div xmlns=\"http://www.w3.org/1999/xhtml\"><p><b>Generated Narrative
with Details</b></p><p><b>id</b>: medication</p><p><b>clinicalStatus</b>: Active
<span>(Details : {http://terminology.hl7.org/CodeSystem/allergyintolerance-clinical
code 'active' = 'Active', given as 'Active'})</span></p><p><b>verificationStatus</b>:
Unconfirmed <span>(Details : {http://terminology.hl7.org/CodeSystem/
allergyintolerance-verification code 'unconfirmed' = 'Unconfirmed', given as
'Unconfirmed'})</span></p><p><b>category</b>: medication</p><p><b>criticality</b>:
high</p><p><b>code</b>: Penicillin G <span>(Details : {RxNorm code '7980' =
'Penicillin G', given as 'Penicillin G'})</span></p><p><b>patient</b>: <a>Patient/
example</a></p><p><b>recordedDate</b>: 01/03/2010</p><p><b>recorder</b>:
<a>Practitioner/13</a></p><h3>Reactions</h3><table><tr><td>-</
td><td><b>Manifestation</b></td></tr><tr><td>*</td><td>Hives <span>(Details : {SNOMED
CT code '247472004' = 'Weal', given as 'Hives'})</span></td></tr></table></div>"
  },
  "clinicalStatus": {
    "coding": [
      {
        "system": "http://terminology.hl7.org/CodeSystem/allergyintolerance-clinical",
        "code": "active",
        "display": "Active"
      }
    ]
  },
  "verificationStatus": {
    "coding": [
      {
        "system": "http://terminology.hl7.org/CodeSystem/allergyintolerance-
verification",
        "code": "unconfirmed",
        "display": "Unconfirmed"
      }
    ]
  },
  "category": [
    "medication"
  ],
  "criticality": "high",
  "code": {
    "coding": [
      {
        "system": "http://www.nlm.nih.gov/research/umls/rxnorm",
        "code": "7980",
        "display": "Penicillin G"
      }
    ]
```



```
  },
  "patient": {
    "reference": "Patient/example"
  },
  "recordedDate": "2010-03-01",
  "recorder": {
    "reference": "Practitioner/13"
  },
  "reaction": [
    {
      "manifestation": [
        {
          "coding": [
            {
              "system": "http://snomed.info/sct",
              "code": "247472004",
              "display": "Hives"
            }
          ]
        }
      ]
    }
  ]
}
```


Using SNOMED CT concepts in FHIR® resources

The SNOMED on FHIR group can provide help and direction on how to deal with the specific issues that may arise when using SNOMED CT concepts in FHIR® resources. SNOMED CT implementation in FHIR guidance can be found here: http://build.fhir.org/ig/IHTSDO/snomed-ig/, while proposals of SNOMED CT adapted FHIR resources can be found here: http://build.fhir.org/ig/IHTSDO/snomed-ig/profiles.html.

You will note that there are two separate FHIR® profiles proposed on this page, based on the general HL7 FHIR AllergyIntolerance resource. One is substance-focused, meaning that the record centers for the AllergyIntolerance.code value on the substance the patient reacts to and captures separately the type of reaction in the AllergyIntolerance.type element. One can say this model captures the allergy/intolerance to X in a post-coordinated way. The second profile is finding-focused, meaning it captures the allergy/intolerance in the AllergyIntolerance.code element using pre-coordinated "allergy/intolerance to X" SNOMED CT concepts and makes no use of the AllergyIntolerance.type element.

4.2 Terminology Bindings

SNOMED CT value sets for use in adverse sensitivity documentation generally belong to two types 1) concepts related to the adverse sensitivity per se, i.e. the adverse sensitivity condition/propensity, adverse sensitivity reactions, and products/substances which are claimed to cause adverse sensitivity reactions; and 2) qualifiers or modifiers e.g. clinical status, verification status, criticality, or severity of adverse reaction. Value sets of the first type usually encompass a large number of concepts and are defined intentionally. Value sets of the second type are usually small and enumerated as a list. Different information models have their own definitions and requirements for value sets. In the following discussion, we will focus on the FHIR® AllergyIntolerence base resource

The FHIR AllergyIntolerence base resource is open to various choices of representation for the adverse sensitivity content per se, but often has restricted ways of providing qualifiers and modifiers.

Adverse sensitivity content value sets

The FHIR AllergyIntolerance base resource has example bindings to SNOMED CT for the element AllergyIntolerance.code as well as elements reaction.substance, reaction.manifestation, and reaction.exposureRoute. All example value sets are though very broad and likely not very precise in determining the set of relevant concepts, see table below. For each data element, the number of concepts that are in the Global Patient Set (GPS) is shown here. The GPS is a special SNOMED CT subset that can be used globally with minimal restriction and at no cost.

FHIR element	SNOMED CT value set	Corresponding ECL	# concepts (in GPS version 2020-7-31)
AllergyIntolerance.code	https://www.hl7.org/fhir/valueset-allergyintolerance-code.html	If recording is based on substances and products and specifies the type of reaction in "type": <<105590001 | Substance (substance) | OR <<373873005 | Pharmaceutical / biologic product (product) | OR If recording is based on finding concepts precoordinating the type of reaction : <<418038007 |Propensity to adverse reactions to substance| OR When using precoordianted Situation concepts to represent the absence of an allergic propensity <<716186003 |No known allergy|[1]	51133 (1157)
AllergyIntolerance. reaction.substance	https://www.hl7.org/fhir/valueset-substance-code.html	<<105590001 | Substance (substance) | OR <<373873005 | Pharmaceutical / biologic product (product) |	49763 (1132)
AllergyIntolerance. reaction.manifestation	https://www.hl7.org/fhir/valueset-clinical-findings.html	<<404684003 |Clinical finding|	114493 (12135)
AllergyIntolerance. reaction.exposureRoute	https://www.hl7.org/fhir/valueset-route-codes.html	<<284009009 |Route of administration value|	163 (20)

Since the SNOMED CT value sets in this category usually include a large number of concepts, implementers often ask for lists of most frequently used concepts to facilitate implementation (e.g., building picklists to assist data entry). These frequently-used subsets are sometimes called “starter sets”. Examples of starter sets are:

Source	Name of value set	Steward	Number of concepts
Value Set Authority Center (VSAC), NLM[2]	Common dietary substances for allergy and intolerance documentation	HL7 Patient Care Workgroup	127
Value Set Authority Center (VSAC), NLM	Common drug classes for allergy and intolerance documentation	HL7 Patient Care Workgroup	42
Value Set Authority Center (VSAC), NLM	Common environmental substances for allergy and intolerance documentation	HL7 Patient Care Workgroup	15

Value Set Authority Center (VSAC), NLM	Common substances for allergy and intolerance documentation including refutations	HL7 Patient Care Workgroup	747 (also includes RxNorm entities)
Value Set Authority Center (VSAC), NLM	Food Allergen	Partners Healthcare	518
HL7	Allergy intolerance substance condition (GPS) – IPS[3]	FHIR GPS IG	784
HL7	Allergy Reaction (GPS) - IPS[4]	FHIR GPS IG	31
eHealth Digital Service Infrastructure (eHDSI)	IPS Allergy or Intolerance Conditions[5]	epSOS	15
eHealth Digital Service Infrastructure (eHDSI)	eHDSIAllergenNoDrug[6]	epSOS	158
eHealth Digital Service Infrastructure (eHDSI)	eHDSIAdverseEventType[7]	epSOS	10

Qualifier and/or modifier value sets

As a result of a request from HL7 to SNOMED International about the possibility of mapping some of the required HL7® FHIR® Value Sets to SNOMED CT, an analysis of the ability of SNOMED CT to accommodate those needs was performed by the SNOMED CT on FHIR Workgroup. The required value sets of the FHIR AllergyIntolerance resource was included in this analysis.

A particular issue with qualifiers/modifiers is they have a strong dependence on what they qualify or modify, and that linkage is provided specifically by the information model at hand. Taking those concepts out of their information model context, which, debatably, mapping those concepts to SNOMED CT entail, could be a challenge.

In the analysis of the FHIR AllergyIntolerance required value sets, all but two were problematic in at least some way. The two straightforward mappable value sets were for elements AllergyIntolerance.reaction.severity and AllergyIntolerance.type

AllergyIntolerance.Reaction.Severity

It was assessed that there was a good match between the HL7 required value set and the SNOMED CT << 272141005 |Severities (qualifier value)| subhierarchy.

HL7 Code	HL7 Display	Suggested SNOMED CT concept
severe	Severe	24484000 |Severe (severity modifier) (qualifier value)|
moderate	Moderate	6736007 |Moderate (severity modifier) (qualifier value)|
mild	Mild	255604002 |Mild (qualifier value)|

AllergyIntolerance.Type

The group's suggested approach here is to use concepts taken from <<609433001 |Hypersensitivity disposition (finding)|unless an actual immune mediated hypersensitivity has been proven e.g., by testing. See section 6.1.1 Allergy list for a further discussion of the rationale behind this approach.

HL7 Code	HL7 Display	Suggested SNOMED CT concept
allergy	Allergy	609433001 |Hypersensitivity disposition (finding)|

HL7 Code	HL7 Display	Suggested SNOMED CT concept
intolerance	Intolerance	782197009 |Intolerance to substance (finding)|

For other required value sets in the FHIR AllergyIntolerance resource there were issues ranging from some concepts in the FHIR value set lacked a corresponding SNOMED CT concept to differences in the underlying ontology making mapping complicated and likely less useful. For more details about mapping FHIR value sets to SNOMED CT, refer to the discussion of the SNOMED on FHIR Workgroup.[8]

[1] The modeling of propensities to adverse reactions has changed since the FHIR resource was published and a single concept now subsumes both allergies and intolerances

[2] https://vsac.nlm.nih.gov/

[3] http://hl7.org/fhir/uv/ips/ValueSet-allergy-intolerance-substance-condition-gps-uv-ips.html

[4] http://hl7.org/fhir/uv/ips/ValueSet-allergy-reaction-gps-uv-ips.html

[5] http://art-decor.org/decor/services/RetrieveValueSet?id=2.16.840.1.113883.11.22.10&effectiveDate=2017-03-29T00:00:00&prefix=hl7ips-&format=html&collapsable=true&language=en-US&ui=en-US

[6] https://art-decor.ehdsi.eu/html/publication/epSOS/epsos-html-20201215T191920/voc-1.3.6.1.4.1.12559.11.10.1.3.1.42.19-2020-04-23T160000.html

[7] https://art-decor.ehdsi.eu/html/publication/epSOS/epsos-html-20201215T191920/voc-1.3.6.1.4.1.12559.11.10.1.3.1.42.18-2020-04-22T093000.html

[8] https://confluence.ihtsdotools.org/display/FHIR/Free+SNOMED+CT+set+for+FHIR

4.3 Examples

Use Case 1: Documentation of Information Related to Allergy, Hypersensitivity, and Intolerance

Scenario 1.1 Documentation of an adverse reaction to a drug substance

Scenario: A physician sees a patient in clinic for routine outpatient care. Recently the patient was prescribed penicillin V 500 mg orally two times daily x 10 days for streptococcal pharyngitis. He tells the physician that he has developed hives the previous week and on examination, the physician confirms the presence of generalized hives. He records this in the patient record as an Observation.

FHIR Observation resource query from patient record (see FHIR representation here)		
Attribute	**Value**	**SNOMED CT concept**
code*	LOINC: 80343-7 |Skin assessment [Interpretation] |	271303006 |Examination of skin (procedure)|
Status	final	-
category	Exam	-
valueCodableConcept		247472004 |Wheal (finding)|
bodySite		39937001 |Skin structure (body structure)|

*LOINC codes are the recommended coding system for the FHIR observation.code element but the observation.code being a CodableConcept, one may choose also to use SNOMED CT concepts to represent the value in this field.

A review of systems fails to reveal any other causes and the physician believes that the patient may be having an urticarial reaction to penicillin. He has lingering uncertainty about this and tells the patient to stop the penicillin and employ diphenhydramine for relief. He schedules him back in a week for follow-up and when recording his note for the visit, he adds to his assessment in the problem list: “Moderate urticarial reaction, possible penicillin allergy”.

FHIR Condition resource query from patient record (see FHIR representation here)		
Attribute	**Value**	**SNOMED CT concept**
code	Urticarial reaction	126485001 |Urticaria (disorder)|
clinicalStatus	active	55561003 |Active (qualifier value)|
verificationStatus	confirmed	410605003 |Confirmed present (qualifier value)|
category	problem-list-item	-
severity	moderate	6736007 |Moderate (severity modifier) (qualifier value)|
bodySite		39937001 |Skin structure (body structure)|

A week later, the patient returns for follow-up with the itching and rash entirely resolved. He reports that the reaction subsided within days after stopping the penicillin. The physician adds “Penicillin allergy probable: moderate reaction of hives; criticality unable-to-assess” to the allergy list.

FHIR resource query from patient record (see FHIR representation here); EHR using a substance focused AllergyIntolerance resource		
Attribute	**FHIR code**	**SNOMED CT concept**
code		764146007 |Penicillin (substance)|
type	allergy	609328004 |Allergic disposition (finding)|*
clinicalStatus	active	55561003 |Active (qualifier value)|
verificationStatus	unconfirmed	415684004 |Suspected (qualifier value)|
category	medication	-
criticality	unable-to-assess	-
reaction.manifestation		247472004 |Wheal (finding)|
reaction.severity	moderate	6736007 |Moderate (severity modifier) (qualifier value)|*
reaction.exposureRoute		26643006 |Oral route (qualifier value)|

Or

FHIR resource query from patient record (see FHIR representation here); EHR using a finding focused AllergyIntolerance resource		
Attribute	**FHIR code**	**SNOMED CT concept**

code		91936005 |Allergy to penicillin (finding)|
type	-	-
clinicalStatus	active	55561003 |Active (qualifier value)|
verificationStatus	unconfirmed	415684004 |Suspected (qualifier value)|
category	medication	-
criticality	unable-to-assess	-
reaction.manifestation		247472004 |Wheal (finding)|
reaction.severity	moderate	6736007 |Moderate (severity modifier) (qualifier value)|*
reaction.exposureRoute		26643006 |Oral route (qualifier value)|

*The use of a SNOMED CT concept to represent theses values requires the use of a FHIR extension in HL7® FHIR® v4.3.0: R4B - STU (see 2.2.3.1).

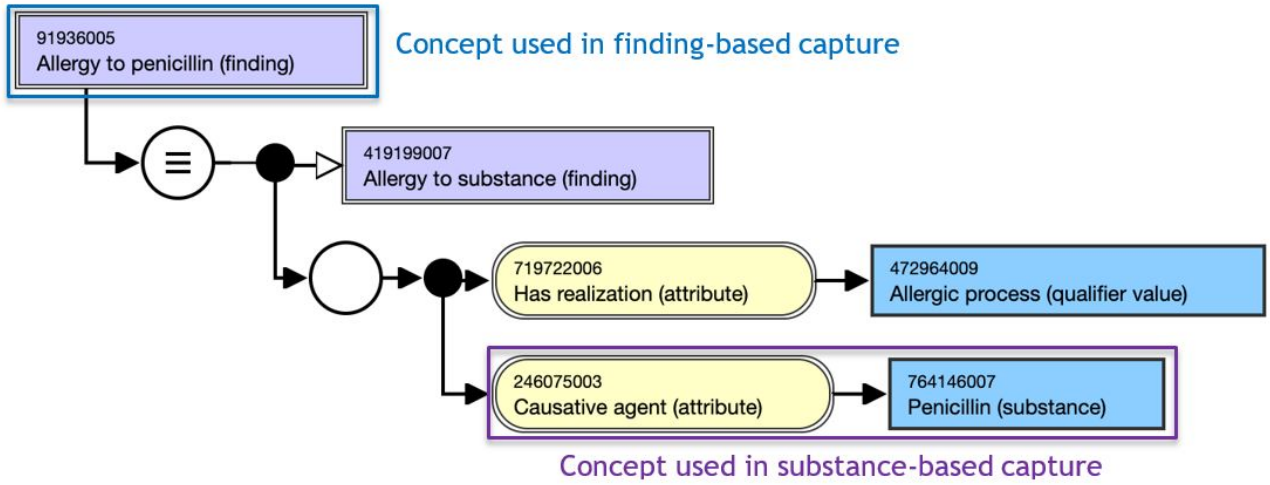


Figure 11: SNOMED CT inferred definition of concept 91936005 |Allergy to penicillin (finding)|as in the International Edition version 20220831.

Scenario 1.2 Documentation in drug allergy list by provider and use as allergy alert

Scenario: Several years later, the same patient who has since received an aortic valve replacement is seeing another physician within the organization for consultation on antibiotic prophylaxis for an upcoming dental procedure. The second physician decides that a penicillin class antibiotic is appropriate for the patient.

When the physician creates an order for amoxicillin 2 g orally as a single dose and commits to the electronic prescription, an alert appears which requires a response by the physician warning him of an allergy history to penicillin. The substance-based alert is generated by the EHR drug-disease interactions software, which uses the Allergy list as a reference. As the patient has not received penicillin class antibiotics for several years, the physician decides to refer the patient to an allergy specialist for clarification of current status of penicillin allergy.

The specialist performs skin testing for penicillin allergy, the results of which are positive. The patient is confirmed as penicillin allergic and the results of the testing are documented in the patient's medical record.

The patient is subsequently prescribed azithromycin for his dental procedure.

FHIR Observation resource for the positive skin test (see FHIR representation here)

Attribute	FHIR code	SNOMED CT concept
code*		252515007 |Type 1 hypersensitivity skin test (procedure)|
status	final	-
category	procedure	-
valueCodableConcept		10828004 |Positive (qualifier value)|
bodySite		39937001 |Skin structure (body structure)|

FHIR resource query from patient record (see FHIR representation here); EHR using a substance focused AllergyIntolerance resource		
Attribute	**FHIR code**	**SNOMED CT concept**
code		764146007 |Penicillin (substance)|
type	allergy	609328004 |Allergic disposition (finding)|*
clinicalStatus	active	55561003 |Active (qualifier value)|
verificationStatus	refuted	410605003 |Confirmed present (qualifier value)|
category	medication	-

Or

FHIR resource query from patient record (see FHIR representation here); EHR using a finding focused AllergyIntolerance resource		
Attribute	**FHIR code**	**SNOMED CT concept**
code		91936005 |Allergy to penicillin (finding)|
type	-	-
clinicalStatus	active	55561003 |Active (qualifier value)|
verificationStatus	refuted	410605003 |Confirmed present (qualifier value)|
category	medication	-

*The use of a SNOMED CT concept to represent theses values requires the use of a FHIR extension in HL7® FHIR® v4.3.0: R4B - STU (see 2.2.3.1).

Scenario 1.3 Documentation of a food intolerance

Scenario: A 34-year-old female is seen by her primary care provider for complaints of abdominal pain, bloating and change in bowel habits within hours or a few days after ingesting whole wheat bread. In addition, she complains of feeling tired but denies itching rash or wheezing. Those complaints are entered as observations in the EHR.

FHIR Condition resource query from patient record (see FHIR representation here)		
Attribute	**FHIR code**	**SNOMED CT concept**
code	-	116289008 |Abdominal bloating (finding)| 21522001 |Abdominal pain (finding)| 84229001 |Fatigue (finding)|

clinicalStatus	active	55561003 |Active (qualifier value)|
verificationStatus	confirmed	410605003 |Confirmed present (qualifier value)|
category	problem-list-item	-

Due to a family history of celiac disease, tissue transglutaminase IgG and IgA are ordered which are negative. The patient is also referred to a gastroenterologist, who performs an endoscopic biopsy, which is negative for celiac disease. (Both of these examination results can be recorded in the EHR as a FHIR observation using LOINC codes).

The patient is advised to avoid wheat and gluten containing products. An encounter diagnosis of moderate wheat intolerance is documented in the patient's health record and wheat is entered in the patient's "allergy" list.

FHIR Condition resource query from patient problem list record (see FHIR representation here)		
Attribute	**FHIR code**	**SNOMED CT concept**
code		700095006 |Intolerance to wheat (finding)|
clinicalStatus	active	55561003 |Active (qualifier value)|
verificationStatus	unconfirmed	415684004 |Suspected (qualifier value)|
category	Encounter-diagnosis	-
severity	moderate	6736007 |Moderate (severity modifier) (qualifier value)|
bodySite		5668004 |Lower gastrointestinal tract structure (body structure)|

FHIR resource query from patient record (see FHIR representation here); EHR using a substance focused AllergyIntolerance resource		
Attribute	**FHIR code**	**SNOMED CT concept**
code		412071004 |Wheat (substance)|
type	intolerance	782197009 |Intolerance to substance (finding)|*
clinicalStatus	active	55561003 |Active (qualifier value)|
verificationStatus	confirmed	410605003 |Confirmed present (qualifier value)|
category	food	-
criticality	low	-
reaction.manifestation		116289008 |Abdominal bloating (finding)| 21522001 |Abdominal pain (finding)|
reaction.severity	moderate	6736007 |Moderate (severity modifier) (qualifier value)|*
reaction.exposureRoute		26643006 |Oral route (qualifier value)|

Or

FHIR resource query from patient record (see FHIR representation here); EHR using a finding focused AllergyIntolerance resource		
Attribute	**FHIR code**	**SNOMED CT concept**
code		700095006 |Intolerance to wheat (finding)|

type	-	-
clinicalStatus	active	55561003 |Active (qualifier value)|
verificationStatus	confirmed	410605003 |Confirmed present (qualifier value)|
category	food	-
criticality	low	-
reaction.manifestation		116289008 |Abdominal bloating (finding)| 21522001 |Abdominal pain (finding)|
reaction.severity	moderate	6736007 |Moderate (severity modifier) (qualifier value)|*
reaction.exposureRoute		26643006 |Oral route (qualifier value)|

*The use of a SNOMED CT concept to represent theses values requires the use of a FHIR extension in HL7® FHIR® v4.3.0: R4B - STU (see 2.2.3.1).

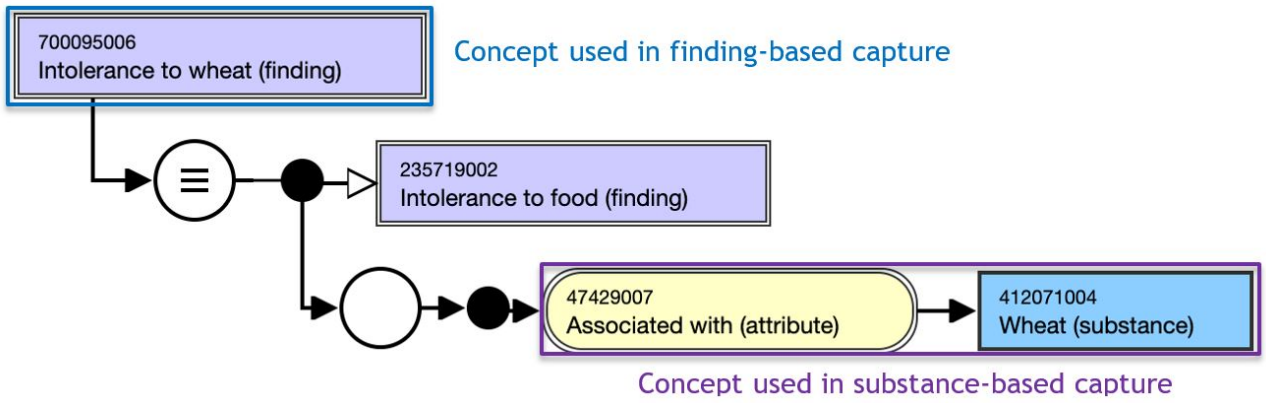


Figure 12: SNOMED CT inferred definition of concept 700095006 |Intolerance to wheat (finding)| as in the International Edition version 20220831.

Scenario 1.4 Documentation of animal allergy or hypersensitivity

The causative agent for the realization of an allergic process directed against a living organism (plant or animal) is not the organism itself or a part of the organism such as epithelium but in most cases is a protein derived from the organism. An allergy to an animal should therefore be modeled with a causative agent that is a descendant of 272169002 |Animal protein (substance)| as in the concept below.

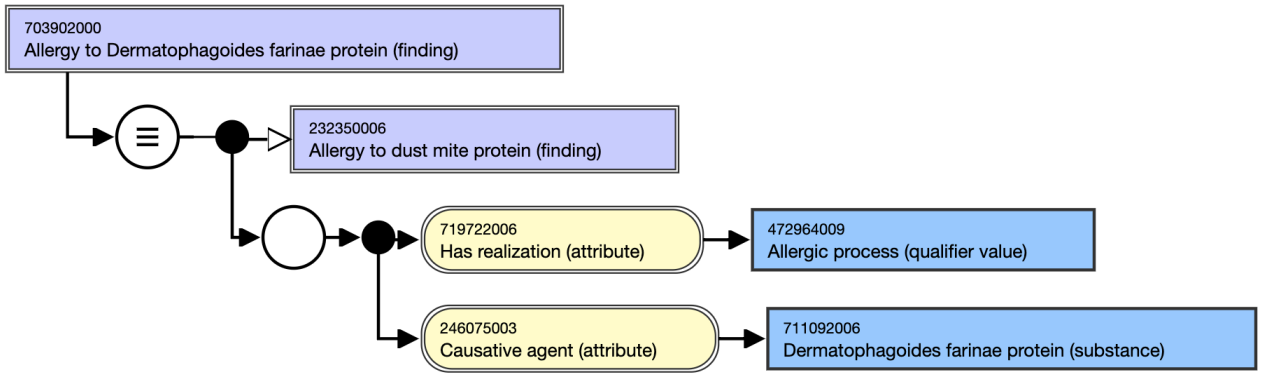


Figure 13: SNOMED CT inferred definition of the concept 703902000 |Allergy to Dermatophagoides farinae protein (finding)| as in the International Edition version 20220831

Likewise animal related material such as dander, feathers, urine, serum, etc. represent sources where the allergenic proteins are found and should not be used as the causative agents for allergy finding and disorder concepts. Allergen sources should only be used as the active ingredients of products containing these materials such as 411572004 |Cat dander diagnostic allergen extract (product)|.

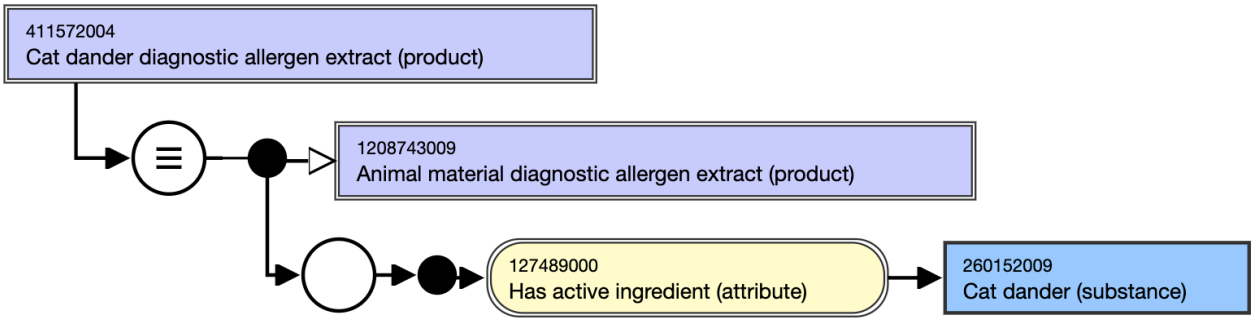


Figure 14: SNOMED CT inferred definition of concept 411572004 |Cat dander diagnostic allergen extract (product)|. Note the *Has active ingredient* attribute using an allergen source concept of Cat dander as target value.

Scenario: A physician sees a patient for the first time in clinic for routine outpatient care. The patient tells the physician that he has begun to experience asthma symptoms. The physician runs some blood tests and a series of skin tests, which demonstrate an intense reaction to the house dust mite, Dermatophagoides farinae protein with high IgE antibody levels.

FHIR Observation resource for the positive IgE lab test (see FHIR representation here)		
Attribute	**FHIR code**	**SNOMED CT concept**
code*	LOINC: 6095-4 American house dust mite IgE Ab [Units/volume] in Serum	388810005 |Dermatophagoides farinae specific immunoglobulin E antibody measurement (procedure)|
status	final	-
category	laboratory	-
valueQuantity	59.1 k[IU]/L	-
interpretation	high	-

* LOINC codes are the recommended coding system for the FHIR observation.code element but the observation.code being a CodableConcept, one may choose also to use SNOMED CT concepts to represent the value in this field.

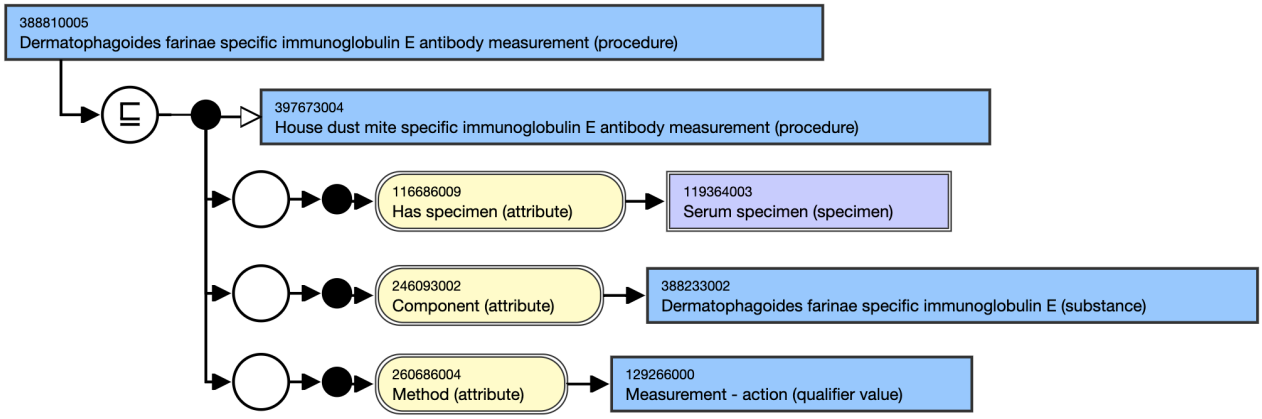


Figure 15: SNOMED CT inferred definition of concept 388810005 |Dermatophagoides farinae specific immunoglobulin E antibody measurement (procedure)| as in the International Edition version 20220831.

The patient confirms that his wheezing occurs primarily at home, especially while lying in bed at night. The physician opens the allergy record and documents the allergic propensity to Dermatophagoides farinae protein, criticality and severity of low in the EHR allergy list.

FHIR resource query from patient record (see FHIR representation here); EHR using a substance focused AllergyIntolerance resource		
Attribute	**FHIR code**	**SNOMED CT concept**
code		711092006 |Dermatophagoides farinae protein (substance)|
type	allergy	609328004 |Allergic disposition (finding)|*
clinicalStatus	active	55561003 |Active (qualifier value)|
verificationStatus	confirmed	410605003 |Confirmed present (qualifier value)|
category	environment	-
criticality	low	-
reaction.manifestation	N/A	195967001 |Asthma (disorder)|
reaction.severity	mild	255604002 |Mild (qualifier value)|*
reaction.exposureRoute		447694001 |Respiratory tract route (qualifier value)|

Or

FHIR resource query from patient record (see FHIR representation here); EHR using a finding focused AllergyIntolerance resource		
Attribute	**FHIR code**	**SNOMED CT concept**
code		703902000 |Allergy to Dermatophagoides farinae protein (finding)|
type	-	-
clinicalStatus	active	55561003 |Active (qualifier value)|
verificationStatus	confirmed	410605003 |Confirmed present (qualifier value)|

category	environment	-
criticality	low	-
reaction.manifestation		195967001 |Asthma (disorder)|
reaction.severity	mild	255604002 |Mild (qualifier value)|*
reaction.exposureRoute		447694001 |Respiratory tract route (qualifier value)|

*The use of a SNOMED CT concept to represent theses values requires the use of a FHIR extension in HL7® FHIR® v4.3.0: R4B - STU (see 2.2.3.1).

Scenario 1.5 Documentation of adverse reaction to a non-medicinal substance cross reacting with a pharmaceutical

Scenario: A patient's mother reports to their child's physician that the child reacts violently to eating peanuts with symptoms that include generalized hives, wheezing and hypotension requiring use of epinephrine for resuscitation. The physician obtains a blood test which documents high levels of IgE antibody against the Arachis h2 peanut protein which is found in unrefined peanut oil (Arachis oil) - the sensitizing agent for clinical peanut allergy. Ara h2 is associated with a risk of severe reactions to peanut. The physician records a peanut allergy in the EHR with anaphylaxis, hives and wheezing as reaction symptoms, records a criticality of high and reaction severity of 'severe'.

FHIR Observation resource for the positive IgE lab test (see FHIR representation here)		
Attribute	**FHIR code**	**SNOMED CT concept**
code*	LOINC: 58778-2|Peanut recombinant (rAra h) 2 IgE Ab [Units/volume] in Serum	445354008 |Measurement of Ara h 2 immunoglobulin E (procedure)|
status	final	-
category	laboratory	-
valueQuantity	>100 k[IU]/L	-
interpretation	high	-

* LOINC codes are the recommended coding system for the FHIR observation.code element but the observation.code being a CodableConcept, one may choose also to use SNOMED CT concepts to represent the value in this field.

FHIR resource query from patient record (see FHIR representation here); EHR using a substance focused AllergyIntolerance resource		
Attribute	**FHIR code**	**SNOMED CT concept**
code		762952008 |Peanut (substance)|
type	allergy	609328004 |Allergic disposition (finding)|*
clinicalStatus	active	55561003 |Active (qualifier value)|
verificationStatus	confirmed	410605003 |Confirmed present (qualifier value)|
category	food	-
criticality	high	-

reaction.manifestation	N/A	39579001|Anaphylaxis (disorder)|
reaction.severity	severe	24484000 |Severe (severity modifier) (qualifier value)|*
reaction.exposureRoute		26643006 |Oral route (qualifier value)|

Or

FHIR resource query from patient record (see FHIR representation here); EHR using a finding focused AllergyIntolerance resource		
Attribute	**FHIR code**	**SNOMED CT concept**
code		91935009 |Allergy to peanut (finding)|
type	-	-
clinicalStatus	active	55561003 |Active (qualifier value)|
verificationStatus	confirmed	410605003 |Confirmed present (qualifier value)|
category	food	-
criticality	high	-
reaction.manifestation		39579001|Anaphylaxis (disorder)|
reaction.severity	severe	24484000 |Severe (severity modifier) (qualifier value)|*
reaction.exposureRoute		26643006 |Oral route (qualifier value)|

*The use of a SNOMED CT concept to represent theses values requires the use of a FHIR extension in HL7® FHIR® v4.3.0: R4B - STU (see 2.2.3.1).

Years later, the youngster is seen by a dermatologist for treatment of acne. As part of the plan of care, the physician enters an electronic prescription for Isotretinoin capsules. When the physician commits the order, the EHR software runs allergy cross checking and issues a high priority alert that the capsules contain peanut oil that is not highly refined and therefore may potentially include peanut protein and are contraindicated for the patient. The physician cancels the order and chooses an alternative preparation.

Scenario 1.6 Documentation of adverse reaction to other non-medicinal substances

Scenario: A licensed nurse presents to her personal physician for recurring problems of a generalized rash and itching. She works in an intensive care unit and is constantly handing chemicals, disinfectants, assisting in surgical procedures and performing catheter cares for her patients. As a part of the health history, she noticed that she had an eruption on her hands after handling latex catheters. Additionally, she reports a serious allergic reaction to papaya in the past and has been careful in the fruits she eats as a consequence. The clinician suspects a latex allergy cross-reacting with foodstuffs and orders IgE testing for Hevea latex antibody. The serology testing is strongly positive and the clinician advises the nurse of his findings with warnings about other foods, which may cross react. While documenting the clinical encounter, he records a latex allergy in the allergy list.

The EHR software supports selection of foods, chemicals and animal biological products as substances, which may be identified as source substances for an entry onto the allergy list or for recording of an adverse reaction.

FHIR Condition resource query from patient record (see FHIR representation here)		
Attribute	**FHIR code**	**SNOMED CT concept**

code	-	271807003|Eruption of skin (disorder)| 418363000 |Itching of skin (finding)|
clinicalStatus	active	55561003 |Active (qualifier value)|
verificationStatus	confirmed	410605003 |Confirmed present (qualifier value)|
category	problem-list-item	-

FHIR Observation resource for the latex IgE level (see FHIR representation here)		
Attribute	**FHIR code**	**SNOMED CT concept**
code	LOINC: 6158-0 |Latex IgE Ab [Units/volume] in Serum|	392475005 |Hevea brasiliensis specific immunoglobulin E antibody measurement (procedure)|
status	final	-
category	laboratory	-
valueQuantity	>100 k[IU]/L	-
interpretation	high	-

* LOINC codes are the recommended coding system for the FHIR observation.code element but the observation.code being a CodableConcept, one may choose also to use SNOMED CT concepts to represent the value in this field.

FHIR resource query from patient record (see FHIR representation here); EHR using a substance focused AllergyIntolerance resource		
Attribute	**FHIR code**	**SNOMED CT concept**
code		1003752001 |Hevea brasiliensis latex protein (substance)|
type	allergy	609328004|Allergic disposition (finding)|*
clinicalStatus	active	55561003 |Active (qualifier value)|
verificationStatus	confirmed	410605003 |Confirmed present (qualifier value)|
category	environment	-
reaction.manifestation		271807003|Eruption of skin (disorder)| 418363000 |Itching of skin (finding)|
reaction.severity	mild	255604002 |Mild (qualifier value)|*
reaction.exposureRoute		6064005|Topical route (qualifier)|

Or

FHIR resource query from patient record (see FHIR representation here); EHR using a finding focused AllergyIntolerance resource		
Attribute	**FHIR code**	**SNOMED CT concept**

code		1003755004 |Allergy to Hevea brasiliensis latex protein (finding)|
type	-	-
clinicalStatus	active	55561003 |Active (qualifier value)|
verificationStatus	confirmed	410605003 |Confirmed present (qualifier value)|
category	environment	-
reaction.manifestation		271807003|Eruption of skin (disorder) 418363000 |Itching of skin (finding)|
reaction.severity	mild	255604002 |Mild (qualifier value)|*
reaction.exposureRoute		6064005|Topical route (qualifier)|

*The use of a SNOMED CT concept to represent theses values requires the use of a FHIR extension in HL7® FHIR® v4.3.0: R4B - STU (see 2.2.3.1).

Scenario 1.7 Recording of 'No known allergies'

Scenario: A nurse is performing an intake examination on a patient that is new to the clinical practice. As part of the clinical interview, he inquires about medication and other allergies. The patient reports that she is not allergic to any medications, foods, chemicals or animals. The nurse opens the 'allergy list' in the EHR and documents 'No known allergies' which electronically validates that the nurse inquired of the patient and that the history was confirmed negative at the date and time recorded. This satisfies decision support criteria that allergies be documented before medication orders are written and is encoded in the EHR allergy list as confirmed absence of dispositions to adverse reactions.

FHIR resource query from patient record (see FHIR representation here); EHR using a finding focused AllergyIntolerance resource		
Attribute	**FHIR code**	**SNOMED CT concept**
code		716186003|No known allergy (situation)|
type	-	-
clinicalStatus	active	55561003 |Active (qualifier value)|
verificationStatus	confirmed	410605003 |Confirmed present (qualifier value)|
category	-	-

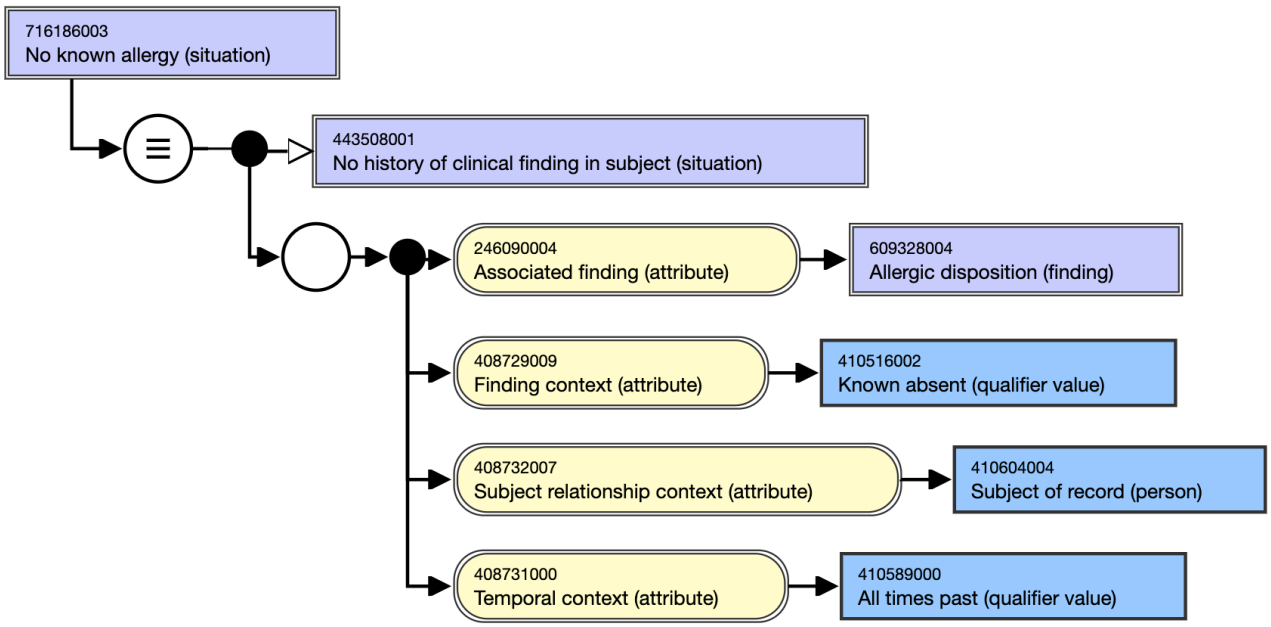


Figure 16: SNOMED CT stated definition of concept 716186003 |No known allergy (situation)| as in the International Edition version 20220131.

Alternatively, the EHR could represent no known allergies by using certainty degree of refuted (confirmed absent) to "negate" the recorded substance concept. This method has the advantage of allowing to record the absence of very specific individual allergies that may not exist in SNOMED CT as pre-coordinated Situation with explicit context concepts. Indeed, it might be interesting to record that the physician has asked specifically if the patient has latex allergy, contrast product allergy, iodine disinfectant allergy, etc. before performing a procedure.

FHIR resource query from patient record (see FHIR representation here); EHR using a substance focused AllergyIntolerance resource		
Attribute	**FHIR code**	**SNOMED CT concept**
code		105590001 |Substance (substance)|
type	allergy	609328004|Allergic disposition (finding)|*
clinicalStatus	active	55561003 |Active (qualifier value)|
verificationStatus	refuted	410594000 |Definitely NOT present (qualifier value)|
category	-	-

*The use of a SNOMED CT concept to represent this value requires the use of a FHIR extension in HL7® FHIR® v4.3.0: R4B - STU (see 2.2.3.1).

Use case 2: Sharing adverse reaction data

Scenario: The patient from Scenario 1.1 is planning a vacation with his family consisting of a cross-country camping trip. In preparation for travels, he speaks to his physician in hospital A and obtains an electronic summary of his healthcare record on a flash drive for himself, his wife and children. His physician informs him that the summary software includes an electronic 'reader' as well as a standard format that can be imported into another EHR for patient care. Their vacation unfolds happily until, many miles from home the patient experiences an episode of right ear pain and is taken to a local emergency room in hospital B. He provides the flash drive with his

electronic record summary to the emergency room physician whose hospital employs an EHR which can accept FHIR extracted electronic record summaries for integration into the on-site health record system. The emergency room nurse loads the flash drive and accepts the electronic copy of the problem list, allergies and medication list into the on-site record. The software extract manages the differences in information model design between EHR vendors by crosschecking the allergy list with information in the problem list and encounter diagnoses.

After an otoscopic exam, the patient is diagnosed with acute otitis media. The emergency room physician enters an electronic order for “875 mg amoxiliin with clavulanate 125 mg orally twice daily”, the drug of choice for acute otitis in adults. When the physician presses ‘Enter’ to commit the order, a pop-up alert is generated by the EHR with warning that this patient has had an allergic reaction to penicillin and has a high likelihood of cross reacting. While studying the alert, the physician notes that the supporting information was gleaned from the problem list and allergy list. The EHR drug interaction software has cross-referenced the chemical composition of amoxillin/clavulanate and noted amoxiliin to be a penicillin derivative. The physician decides that the information of penicillin allergy is credible and as the patient has taken cephalosporins in the past without issues, the physician changes his order to Cefuroxime, 500 mg orally twice daily.

5. Implementation Considerations

Implementing the recording and allergy, hypersensitivity, and intolerance information in clinical records and its use in clinical decision support systems and alerts requires careful consideration of different implementation options, including different information models, bindings, terminology distribution architecture, and compatibility with data exchange standards.

5.1 Options for Documenting Allergy using Allergy List vs Problem List

There are two main ways to document adverse sensitivity in the EHR, which are supported by SNOMED CT. One option is to use a substance-focused model implementing an allergy list, and the other option is to use a findings-focused model implementing a problems list. The documentation of allergy desensitization requires a different model. The implementation approach would be determined by factors such as EHR architecture, user preference and data exchange requirements.

Although the term “allergy” is generally defined as occurring via an immunologic process caused by a misdirected humoral immune response especially involving IgE antibodies or a cell-mediated process, proving this through testing is often not possible, especially for drugs. Most physicians and patients tend to conflate true drug allergy with pseudoallergy (non-allergic hypersensitivity) or interpret allergy more broadly as any adverse drug effect and documentation in EHRs often reflects this uncertainty. For this reason, standards such as HL7® FHIR® and ICD-11 combine the word allergy with allergy-like/clinically resembling allergy and do not distinguish allergy from non-allergic hypersensitivity, which would most closely align with the SNOMED concept, 473010000 |Hypersensitivity condition (finding)| and its disposition and reaction subconcepts.

Allergy list

Allergy or intolerance can be recorded in a specific section (e.g., “Drug Allergy and Intolerance”) of the EHR, which records the causative agent together with other details, including type (allergy, non-allergic hypersensitivity, intolerance), certainty, manifestation, and severity. This corresponds to the FHIR substance based AllergyIntolerance resource data model.

In terms of documenting sensitivity type in the allergy list there is the option to map to 609433001 |Hypersensitivity disposition which in SNOMED CT represents both immune-mediated and non-immune mediated hypersensitivity or to map to 609328004 |Allergic disposition (finding)|which is common clinical parlance for what many clinicians would mean by allergic or non-allergic hypersensitivity. In addition, as recommended in the FHIR documentation if one is unclear as to whether a condition represents hypersensitivity or intolerance, one can just omit the type element from the resource.

If SNOMED CT concepts are used to document the causative agent, it is preferable to use concepts from the Substance rather than Pharmaceutical/biologic product hierarchy since this will facilitate the downstream use of data, e.g., clinical decision support, data exchange.

Almost all allergy and intolerance finding concepts are modeled using substance concepts in SNOMED CT. The SNOMED CT substance hierarchy has grouper concepts that are based on structure (e.g., Macrolide) or disposition (e.g., substance with histamine receptor antagonist mechanism of action). Clinical decision support systems can utilize these grouper concepts to access information at the desired level of granularity. Clinicians can also record a class of substance instead of a specific drug or substance (e.g., angiotensin II receptor antagonist). Note that substance grouper concepts based on therapeutic role (e.g., anticonvulsant) is not recommended for use because they are currently under review and may be retired in future.

There are situations in which it is difficult to determine the specific substance as a true cause or most likely cause of a condition. This is the case for allergy/intolerance to a product containing multiple substances.

Records of allergy to multiple substances or to multi-ingredient products should be recorded at the product level and updated when more specific information becomes available (e.g., positive sensitivity test to one specific ingredient of the mix).

Problem list

Allergy or intolerance can also be recorded in the EHR as a problem. The problem list is normally restricted to SNOMED CT concepts from three hierarchies – Clinical finding, Event and Finding with explicit context. This corresponds either to the FHIR finding based AllergyIntolerance resource data model or the FHIR Condition resource.

For practical guidance using SNOMED CT to document hypersensitivity to specific substances in a problem list, it is suggested to map to the appropriate concepts under the 473011001 |Allergic condition (finding)|hierarchies. This is due to the lack of sufficient content under 609433001 |Hypersensitivity disposition (finding)|and 421961002 |Hypersensitivity reaction (disorder)|and that many of the concepts under 609328004 |Allergic disposition (finding)| and 419076005 |Allergic reaction (disorder)|have unclear mechanisms which may actually represent non-allergic hypersensitivity. Please note that SNOMED international does not plan to create new children concepts of hypersensitivity disposition to specific substances unless more than one Member country would submit a request for them to answer to an active use-case.

Almost all allergy concepts are modeled by substances in SNOMED CT. A very small number of allergy concepts are modeled by products but with explicit description for the specific intended meaning. Records of allergy to multiple substances or to multi-ingredient products should be recoded at the product level and updated when more specific information becomes available (e.g., positive sensitivity test to one specific ingredient of the mix).

Vaccine allergy is an example where allergy concepts are modeled using a product concept. For example, 'Allergy to component of vaccine product (finding)' with a synonym 'vaccine allergy' has been modeled by vaccine product. The concept represents that allergy is caused by any substance in a vaccine product.

To record the level of certainty or verification status, it is recommended to use additional data elements in the EHR information model. Even though it is possible to utilize the SNOMED CT model for 'situation with explicit context' to express certainty, this is not recommended due to potential ambiguity. For example, "suspected penicillin allergy" can mean uncertainty with the condition (is it real allergy?) or with the causative agent (is it penicillin?). Even though SNOMED CT editorial guideline is clear that the first interpretation is correct, it is better to use other methods to represent the uncertainty to avoid confusion.

Documentation of Allergy Desensitization

Desensitization (aka hyposensitization) therapy involves the administration of increasing doses of an allergen in order to induce a state of tolerance. Desensitization to inhalant and food allergens (allergen immunotherapy) results in long-term control of symptoms, which may persist after the treatment is discontinued, while drug desensitization induces temporary tolerance only during the course of therapy. In either case, an active status of allergy should not be removed from the medical record in those patients that are undergoing or have completed a course of desensitization therapy. Documentation of patients undergoing specific desensitization protocols using SNOMED CT can be accomplished using the descendants of 367428009 |Desensitization therapy (regime/therapy).

5.2 Enabling Clinical Decision Support

A typical scenario for clinical decision support is when the physician is ordering a drug through the EHR's prescription order entry system, and being alerted of a potential drug allergy. SNOMED CT can be used to implement allergy and intolerance checking. The prerequisite is that the drugs in the order entry system are mapped to SNOMED CT substances. If the allergy or intolerance information is stored in the allergy list, which is already mapped to SNOMED CT substances, allergy checking will be relatively straightforward. If the information is stored as a SNOMED CT-encoded problem, the causative agent can be derived from the concept model. For example, e.g., Allergy to amoxicillin (finding) has an attribute Causative agent with value Amoxicillin (substance).

When SNOMED CT is used in allergy and intolerance checking, the following should be noted:

- Drug class - when the causative agent is recorded as a SNOMED CT drug class, the SNOMED CT hierarchy can be used to check for members of the class. It is recommended to use drug classes that are descendants of Substance categorized by structure (substance) and Substance categorized by disposition (substance), and avoid therapeutic role-based classes.

- Excipient or adjuvant – in some rare cases, the adverse sensitivity is caused by an excipient rather than the active ingredient of a pharmaceutical product. Excipients are not well documented in most drug terminologies, including SNOMED CT. Similarly, allergy to vaccines could be caused by preservatives, egg protein, gelatin, latex, or vaccine adjuvants. In such cases, the SNOMED CT substance hierarchy will not be as useful for decision support, and the allergy list will be populated with the medical product concept.
- Cross reactivity – this is either mediated by immunologic or non-immunologic mechanisms. The former kind is usually explained by the presence of common structural antigenic determinants in the cross-reacting drugs. In the case of compounds provoking non-immunologic hypersensitivity reactions, cross-reactivity is explained by a common pharmacological characteristic, such as the inhibitory effect of non-steroidal anti-inflammatory drugs on cyclooxygenase-1 and the capability of muscle relaxants or contrast media to release histamine through a non-immunologic mechanism. While structural similarity is reflected in the structural categorization of SNOMED CT Substances, the threshold of similarity that should trigger cross reactivity alerts is not well defined. Generally, an external knowledge source outside of SNOMED CT is required for reliable cross reactivity checking.
- Bidirectional allergy checking – Documenting allergy to a drug product containing multiple substances in which the causative substance is known through testing or a high probability requires that documentation of an allergy to the product will trigger an alert if a drug containing only that substance is ordered. Similarly, an allergy to a drug containing a single substance should trigger an alert if a drug product containing that substance is ordered. Decision support systems based on the SNOMED CT product and substance hierarchies will need to be designed to traverse these relationships in both directions in order to trigger the kinds of alerts just described.

5.3 Terminology Services

The recommended approach for implementing SNOMED CT in clinical systems is using standard Terminology Services. HL7 FHIR provides the CodeSystem, Valuesets, and ConceptMaps resources and their corresponding operations to support access to terminologies using a standardized approach.

These are some examples of how FHIR Terminology services can be used to resolve the terminology bindings described in this guide. using a demo FHIR terminology server:

FHIR element	FHIR Terminology Services Expand Operation
AllergyIntolerance.code	If recording is based on substances and products and specifies the type of reaction in "type": <<105590001 | Substance (substance) | OR <<373873005 | Pharmaceutical / biologic product (product) | https://snowstorm.snomedtools.org/fhir/ValueSet/$expand?url=http://snomed.info/sct?fhir_vs=ecl/%3C%3C105590001%20%7C%20Substance%20%28substance%29%20%7C%20OR%20%3C%3C373873005%20%7C%20Pharmaceutical%20%2F%20biologic%20product%20%28product%29%20%7C
	If recording is based on finding concepts precoordinating the type of reaction : <<418038007 |Propensity to adverse reactions to substance| https://snowstorm.snomedtools.org/fhir/ValueSet/$expand?url=http://snomed.info/sct?fhir_vs=ecl/%3C%3C418038007%20%7CPropensity%20to%20adverse%20reactions%20to%20substance%7C
	When using precoordianted Situation concepts to represent the absence of an allergic propensity <<716186003 |No known allergy| https://snowstorm.snomedtools.org/fhir/ValueSet/$expand?url=http://snomed.info/sct?fhir_vs=ecl/%3C%3C716186003%20%7CNo%20known%20allergy%7C

FHIR element	FHIR Terminology Services Expand Operation
AllergyIntolerance. reaction.substance	<<105590001 | Substance (substance) | OR <<373873005 | Pharmaceutical / biologic product (product) | https://snowstorm.snomedtools.org/fhir/ValueSet/$expand?url=http://snomed.info/sct?fhir_vs=ecl/%3C%3C105590001%20%7C%20Substance%20%28substance%29%20%7C%20OR%20%3C%3C373873005%20%7C%20Pharmaceutical%20%2F%20biologic%20product%20%28product%29%20%7C
AllergyIntolerance. reaction.manifestation	<<404684003 |Clinical finding| https://snowstorm.snomedtools.org/fhir/ValueSet/$expand?url=http://snomed.info/sct?fhir_vs=ecl/%3C%3C404684003%20%7CClinical%20finding%7C
AllergyIntolerance. reaction.exposureRoute	<<284009009 |Route of administration value| https://snowstorm.snomedtools.org/fhir/ValueSet/$expand?url=http://snomed.info/sct?fhir_vs=ecl/%3C%3C284009009%20%7CRoute%20of%20administration%20value%7C

5.4 Demonstration app

This open-source implementation demonstration app was created based on the recommendations presented in this guide and using SNOMED International FHIR terminology servers.

Demo site: https://ihtsdo.github.io/sct-implementation-demonstrator/#/allergies

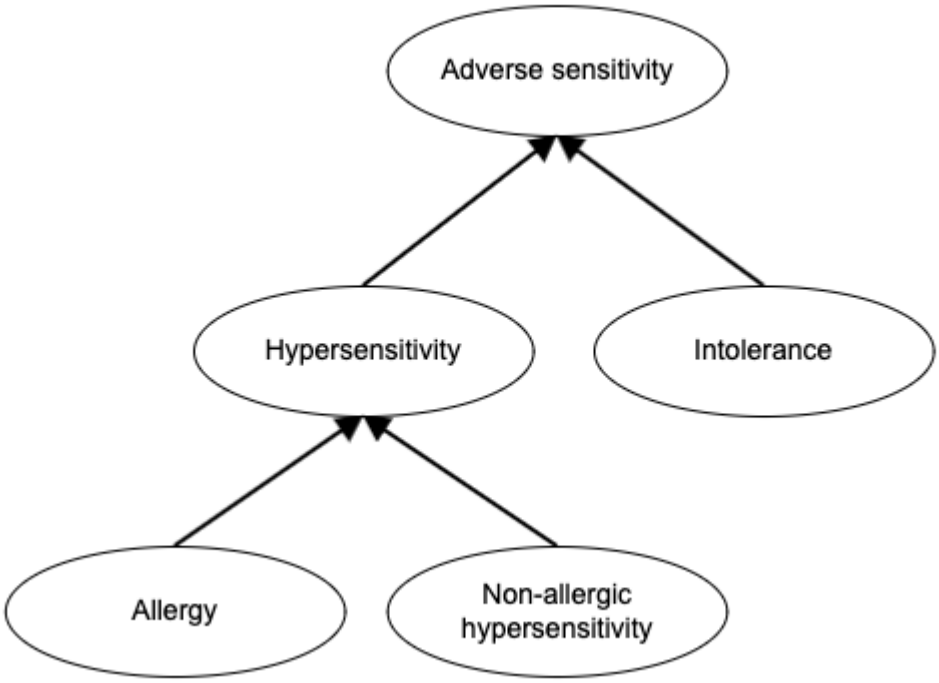
Source code: https://github.com/IHTSDO/sct-implementation-demonstrator

Appendixes

Appendix A: Glossary of Terms

The following table contains the definition of any terms used within this document.

Hierarchy of terms:



Term List:

Term	Definition
Adverse sensitivity	The propensity to developing an untoward effect to a substance at a dose which is tolerated by normal persons. It encompasses allergic and non-allergic hypersensitivity, intolerance and idiosyncrasy
Adverse sensitivity test	A collective term to encompass sensitivity and sensitization tests
Adverse Reaction	An undesirable physiological effect resulting from exposure to a substance.
Allergic condition	The disposition to develop an allergic reaction, the allergic reaction itself or its consequences
Allergic disposition	The disposition to develop an allergic reaction
Allergic reaction	A pathological immune process generally directed towards a foreign antigen, which results in tissue injury, which is usually transient. It is the realization of the allergic disposition. It is most often applied to type I hypersensitivity but other hypersensitivity types especially type IV (e.g. allergic contact dermatitis) may be involved

Allergic sensitization	A process characterized by a humoral or cell-mediated immune response to a foreign antigen resulting in the production of specific antibodies and/or immune cells which may then lead to an allergic disposition.
Intolerance	Any undesirable effect of exposure to low or usual amounts of a substance. Specifically excludes allergy and non-allergic hypersensitivity
Drug intolerance	An undesirable pharmacologic effect that may occur at low or usual doses of the drug. Humoral or cellular immune mechanisms are not thought to be involved, and a scientific explanation for such exaggerated responses has not been established (eg, aspirin-induced tinnitus at low doses). Intolerance encompasses drug idiosyncrasy.
Drug idiosyncrasy	An abnormal and unexpected effect that is unrelated to the intended pharmacologic action of a drug and has an unknown mechanism. It is not mediated by a humoral or cellular immune response but is reproducible on readministration. It may be due to underlying abnormalities of metabolism, excretion, or bioavailability (eg: quinidine-induced drug fever).
Excipient	An ingredient of a drug formulation that is added for reasons other than the primary therapeutic use of the drug. Excipients include preservatives, antibiotics, various vehicles such as emulsifiers and fillers, preservatives, colorizing agents and flavors.
Food intolerance	A food intolerance or a food sensitivity occurs when a person has difficulty digesting a particular food. This can lead to symptoms such as intestinal gas, abdominal pain or diarrhea. A food intolerance is sometimes confused with or mislabeled as a food allergy. Food intolerances involve the digestive system. Food allergies involve the immune system. With a food allergy, even a microscopic amount of the food has the potential to lead to a serious or life-threatening reaction called anaphylaxis. [2]
Hypersensitivity condition	The disposition to develop an allergic or non-allergic hypersensitivity (pseudoallergic) reaction, the reaction itself or its consequences.
Hypersensitivity disposition	The disposition to develop an allergic or non-allergic hypersensitivity (pseudoallergic) reaction
Hypersensitivity reaction	A pathological process initiated by exposure to a defined stimulus at a dose tolerated by normal persons. It is the realization of the disposition to hypersensitivity.
Non-allergic hypersensitivity condition	The disposition to develop a non-allergic hypersensitivity (pseudoallergic) reaction, the pseudoallergic reaction itself or its consequences
Non-allergic hypersensitivity disposition	The disposition to develop a non-allergic hypersensitivity (pseudoallergic) reaction
Non-allergic hypersensitivity reaction	A pathological nonimmune process generally directed towards a foreign substance, which results in tissue injury, which is usually transient. It is the realization of the non-allergic hypersensitivity (pseudoallergic) disposition. A variety of mechanisms such as direct histamine release, complement activation, cyclooxygenase activation and bradykinin generation may be involved
Sensitivity test	A test to confirm clinical sensitivity to a particular substance by exposing an individual to that substance and observing for the onset of signs and symptoms consistent with a hypersensitivity reaction. Commonly referred to as a “challenge” test
Sensitization test	A skin or in vitro test to demonstrate an individual has developed an immune response to an allergen. A positive test does not necessarily indicate that an individual is clinically sensitive to that allergen

References:

1. Joint Task Force on Practice Parameters; American Academy of Allergy, Asthma and Immunology; American College of Allergy, Asthma and Immunology; Joint Council of Allergy, Asthma and Immunology. Drug allergy: an updated practice parameter. Ann Allergy Asthma Immunol. 2010 Oct; 105(4):259-273. doi: 10.1016/j.anai.2010.08.002.

2. Thanai Pongdee. Food Allergy Versus Food Intolerance. Published by American Academy of Allergy Asthma & Immunology 02/2011.

Appendix B: Historical SNOMED CT content perspective

Efforts to revise the allergy-related hierarchies in SNOMED can be traced back to at least 2005 during which time several deficiencies were identified in the modeling of allergies and adverse reactions involving the inconsistent use of the causative agent role and the need to clearly differentiate the propensity to react from the reaction itself in order to better integrate with proposed HL7® models for allergy. Thus, allergy (disorder) was replaced by allergic state (disorder) as a child of 420134006 | Propensity to adverse reactions (disorder) and adverse reactions/allergy to various substances, food and drugs were updated in the 2006 release of SNOMED CT.Additional revisions to the SNOMED CT allergy content occurred in 2006 included an attempt to align the terminology with the nomenclature for allergy developed by the WAO/EAAACI in 2001.

Another update to the allergy terminology was implemented for the July 2013 release of SNOMED CT. This update organized all of the three main allergy classes (conditions, propensities and reactions) which up to this point resided in three unrelated hierarchies under a single “allergy condition” hierarchy. Additionally, the July 2013 release included a more robust concept model for hypersensitivity/allergy conditions, particularly for the allergy propensity class (since named allergic disposition). Text definitions for the major organizing classes were also included for the first time.

Revising SNOMED CT to the three classes model meant that hypersensitivity data were represented by:

- Abnormal structures, which are diseases that may have a finding site and a morphology e.g. allergic rhinitis
- Dispositions (propensities), which model the patient state of an “Allergy to x”. <<420134006|Propensity to adverse reactions(finding)|
- Processes (reactions) Example: “Allergic reaction to x”. <<281647001|adverse reaction (disorder)|
- Conditions, which represent disorders characterized by abnormal structures, propensities that may be realized as pathologic processes (i.e. reactions) or the reactions themselves.
    - Example
        - 473011001 |Allergic condition (finding)|
            - 781474001 |Allergic disorder (disorder)|
            - 419076005 |Allergic reaction (disorder)|
            - 609328004 |Allergic disposition (finding)|

Appendix C: Analysis of the HL7 C-CDA model

C.1 HL7 C-CDA model

The Consolidated Clinical Document Architecture (C-CDA) specification (release 1.1 and 2.0) is required for communication of clinical data at transitions of care by the Office of the National Coordinator (ONC) for Health IT in the US. The ONC 2015 Edition Final Rule updated this requirement to specify the 2.1 version for Meaningful Use Stage 3 certification. The 2.1 C-CDA version includes an updated Allergy - Intolerance Observation (V2) 2.16.840.1.113883.10.20.22.4.7 template which includes a new Criticality Observation 2.16.840.1.113883.10.20.22.4.145 (replacing the previous Severity Observation (V2) at the allergy propensity level – the Severity Observation (V2) continues to be used in the Reaction Observation (V2)). The other relevant templates for use cases in section 3 are: Allergy Concern Act (V3) 2.16.840.1.113883.10.20.22.4.30 and Result Observation (V2) 2.16.840.1.113883.10.20.22.4.2.

The latest information about the HL7® C-CDA® standard can be found here: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=492

C.2 Allergy Concern Act (V3)

This template reflects an ongoing concern on behalf of the provider that placed the allergy on a patient’s allergy list. As long as the underlying condition is of concern to the provider (i.e., as long as the allergy, whether active or resolved, is of ongoing concern and interest to the provider), the statusCode is “active”. Only when the underlying

allergy is no longer of concern is the statusCode set to “completed”. The effectiveTime reflects the time that the underlying allergy was felt to be a concern.

The statusCode of the Allergy Concern Act is the definitive indication of the status of the concern, whereas the effectiveTime of the nested Allergy - Intolerance Observation is the definitive indication of whether or not the underlying allergy is resolved.

The effectiveTime/low of the Allergy Concern Act asserts when the concern became active. This equates to the time the concern was authored in the patient's chart. The effectiveTime/high asserts when the concern was completed (e.g., when the clinician deemed there is no longer any need to track the underlying condition).

C.3 Allergy - Intolerance Observation (V2)

This template reflects a discrete observation about a patient's allergy or intolerance. Because it is a discrete observation, it will have a statusCode of "completed". The effectiveTime, also referred to as the "biologically relevant time" is the time at which the observation holds for the patient. For a provider seeing a patient in the clinic today, observing a history of penicillin allergy that developed five years ago, the effectiveTime is five years ago.

The effectiveTime of the Allergy - Intolerance Observation is the definitive indication of whether or not the underlying allergy/intolerance is resolved. If known to be resolved, then an effectiveTime/high would be present. If the date of resolution is not known, then effectiveTime/high will be present with a nullFlavor of "UNK".

The agent responsible for an allergy or adverse reaction is not always a manufactured material (for example, food allergies), nor is it necessarily consumed. The following constraints reflect limitations in the base CDA R2 specification, and should be used to represent any type of responsible agent, i.e., use playingEntity classCode = "MMAT" for all agents, manufactured or not.

C.4 Result Observation (V3)

This template represents the results of a laboratory, radiology, or other study performed on a patient.

The result observation includes a statusCode to allow recording the status of an observation. “Pending” results (e.g., a test has been run but results have not been reported yet) should be represented as “active” ActStatus.

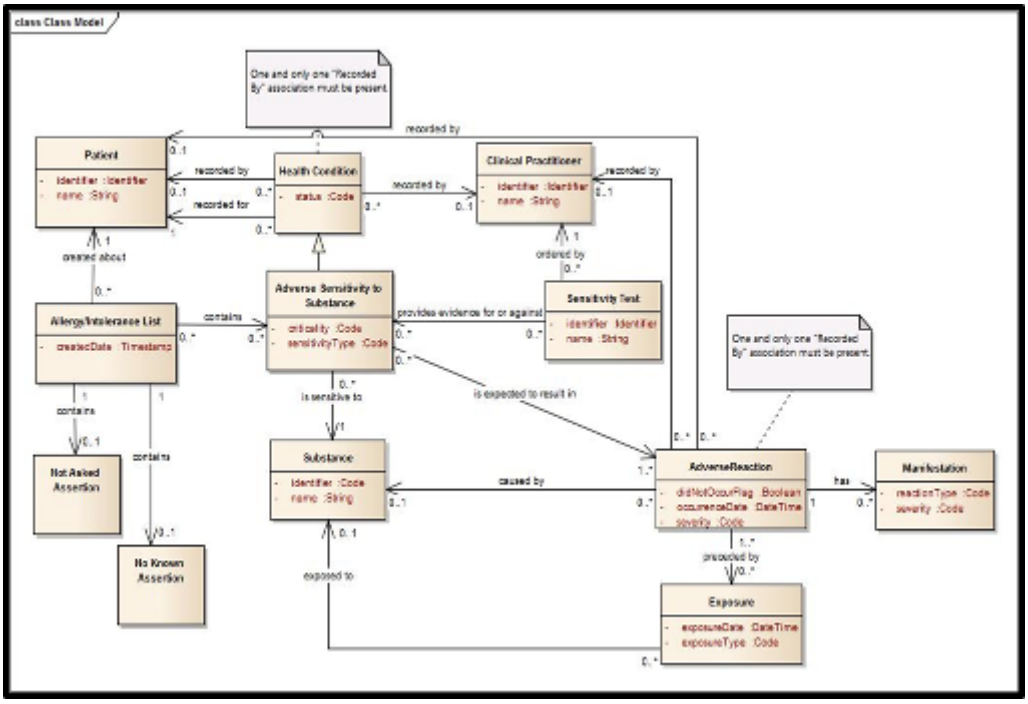
For examples of C-CDA templates, see the C-CDA implementation guide.

Appendix D: Analysis of the HL7 Patient Care Domain Analysis Model

This domain analysis model for allergy records was developed by the HL7 Patient Care Work Group and has been used to inform the allergy/intolerance modeling in the C-CDA® and FHIR® specifications.

http://www.hl7.org/implement/standards/product_brief.cfm?product_id=308

Figure 7: Patient Care Domain Analysis Model



Selected attribute definitions

Attribute name	Datatype	Definition
Adverse reaction		
severity	Coded	Assessment of the severity of the reaction
didNotOccurFlag	Boolean	Indicates a reaction did not occur at contact with substance
OccurrenceDate	DateTime	Time stamp for manifestation of the reaction
Health condition		
status	Coded	Current status of the concern
Adverse sensitivity to substance		
criticality	Coded	Clinical judgement regarding potential seriousness of a future reaction.
sensitivityType	Coded	Allergy; intolerance
createdDate	Date Time	Date time the entry was created
Substance		
identifier	Coded	Coded reference to the substance involved in the reaction
name	String	Name of the substance
Exposure		
exposureDate	Date Time	Date time when the exposure occurred; may be approximated
exposureType	Coded	How the exposure occurred, eg vaccination, prescription, administration, accidental

Attribute name	Datatype	Definition
Manifestation		
severity	Coded	Severity of the manifestation of the reaction
reactionType	Coded	Clinical finding characterizing the reaction, eg code for rash or hives
Sensitivity test		
identifier	Identifier	Identifier pointing to results of the sensitivity test
name	String	Name of the test

Appendix E: Analysis of the ISO International Patient Summary (IPS)

The IPS is designed to provide clinical information to assist care across any jurisdictional (e.g. local, regional, state/provincial, national) or organizational border by providing a minimal but not exhaustive data set useful for subsequent clinical care scenarios. It emphasizes the data required and the associated business rules to support use and the necessary conformance of the use case for an international patient summary. The ISO TC215 International Patient Summary includes a section on Allergies and Intolerances.

The IPS includes the following conformance attributes:

M	Mandatory	Shall always be present and - where applicable - shall be instantiated with valid values. No exceptions or empty/null values are allowed in this case.
R	Required	A required element shall always be present and - where applicable - should be instantiated with valid values. Exceptions or empty/null values are allowed in this case.
RK	Required if Known	If there is information available, the element must be present and - where applicable - instantiated with valid values. If there is no information available, the element may be omitted, may be left empty, or may be instantiated with exceptional or null values depending on the implementation.
C	Conditional	Depending on predicate conditions, the element may assume different conformance strengths (e.g. O, R, RK) or not being present.
O	Optional	This data element can be omitted from a derived model, including from implementations. Recipient may ignore optional elements.

The Allergies and Intolerance section of IPS data set includes:

Data Element	Conformance	Datatype	Data Element Description
Allergies/Intolerances content status	C	coded	As this IPS Section is mandatory for conformance, information about “known absence of allergies” or no information about allergies is required to be stated. Known Content will be accompanied by the conditional list of Allergies and intolerances.
Allergies and Intolerances	C	List	If present then they shall be listed else give explicit reasons for why none are recorded. An ordered list comprising the name, code, a description of the Allergy/intolerance and Agent details for each Allergy/intolerance.

Data Element	Conformance	Datatype	Data Element Description
1) Allergy/Intolerance	M	Label concept	If allergies present then they shall be listed else give explicit reasons for why none are recorded. An ordered list comprising the name, code, a description of the Allergy/intolerance and Agent details for each Allergy/ intolerance.
a. Allergy/Intolerance description	R	Text	Textual description of the allergy or intolerance.
b. Clinical status	R	Coded	Provides the current status of the allergy or intolerance (e.g., active)
c. Onset date	RK	Datetime	It shall be provided with the highest known precision, at least to the year
d. End Date	C	Datetime	If Clinical Status is non-active then an exception can be raised to indicate inconsistency. It shall be provided with the highest known precision, at least to the year.
e. Criticality	O	Coded	Represents the gravity of the potential risk for future life-threatening adverse reactions when exposed to a substance known to cause an adverse reaction in that individual.
f. Certainty	O	Coded	Assertion about certainty associated with the propensity, or potential risk, of a reaction to the identified substance.
g. Type of propensity	RK	Coded	Type of allergy or intolerance. (e.g., allergy)
h. Diagnosis	O	Coded	A code indicating the type of reaction and the agent; an alternative option for describing an allergy to the agent. (e.g., lactose intolerant)
i. Reaction	RK	Label Concept	A Label Concept recognizing that other data concerning the reaction may be made available in later versions of this standard.
i) Manifestation of the reaction	RK	Coded	Description of the clinical manifestation of the allergic reaction. Example: anaphylactic shock
ii) Severity	RK	Coded	Coded element that describes the subjective assessment of the severity of the condition as evaluated by the clinician, in the case of an allergy it is used as attribute of a manifestation of a reaction.
j. Agent	R	Label Concept	
iii) Agent code	R	Coded	A specific allergen or other agent/substance to which the patient has an adverse reaction propensity.
iv) Category	O	Coded	Allergy substance category (eg food)

Additional information about FHIR® implementation guide of the International Patient Summary can be found here: http://hl7.org/fhir/uv/ips/ .

Appendix F: Analysis of the epSOS information model

Several models were discussed for representing the Allergy information. Especially because there was set a requirement that the information should express the difference between an allergy and intolerance, which have clinically very different meanings. Should be build a model on our own or did a standard models exist which matched our use case? The Semantic team was considering adoption the HL7® CDA/CCD model for allergies where "adverse event type" is used with a terminology such as SNOMED high-level classification, so that the distinction between allergies versus intolerances can be managed. The whole model was not adopted, but a simplified version of it due the fact it contained too many dimensions, which were out of scope for the PS use case.

The distinction between reactions to substances/food versus drugs was also a request and thereby explicit handled, with appropriate value sets.

SNOMED CT was selected for three attributes in the proposed Allergy model:

Reaction Allergy:

The Value Set was selected to code the clinical manifestations of allergy developed by patient in the "Allergies and Other Adverse Reactions" section of the patient Summary (along with epSOSActiveIngredient). This value set was inherited as defined in CDA/CCD Allergy Model, since the choice of the Allergy model was taken.

AdverseEventType:

The value set was selected to cods the patient's kind of adverse reactions against substance, food or drugs. This value set was inherited as defined in CDA/CCD Allergy Model, since the choice of the Allergy model was taken.

Allergen No drugs:

The Value Set was created to code the allergenic agents (apart from drugs) against which the patient has developed an adverse reaction due to the fact that this type of information was not part of the CDA/CCD Allergy Model. The value set was created in a 5-step workflow (created, review by clinician, reviewed by semantic team, revised by clinician, reviewed and approved by Semantic Team). Relevant sub-hierarchies in SNOMED CT were selected and some single terms. The value set was validated by the Semantic Team for acceptance as a minimum value set/data set.

Data element level 1 (cardinality)	Data element level 3 (cardinality)	COMMENTS	BASIC (Basic) / EXTENDED (Ext) DATASET	Null flavour Yes/No
Allergy	Allergy Display name		Basic	Yes
	Allergy code	The code of the allergy	Basic	Yes
	Onset date	Date when the allergy started	Ext	No
	Agent description	Description of the allergen agent	Basic	Ext
	Agent code	The code of the allergen agent	Basic	Ext

Value Sets:

epSOSReactionAllergy

2.16.840.1.113883.6.96

If referred to the type (e.g. not allergic intolerance)

epSOSAdverseEventType

2.16.840.1.113883.6.96

WHO ATC

2.16.840.1.113883.6.73

If not:

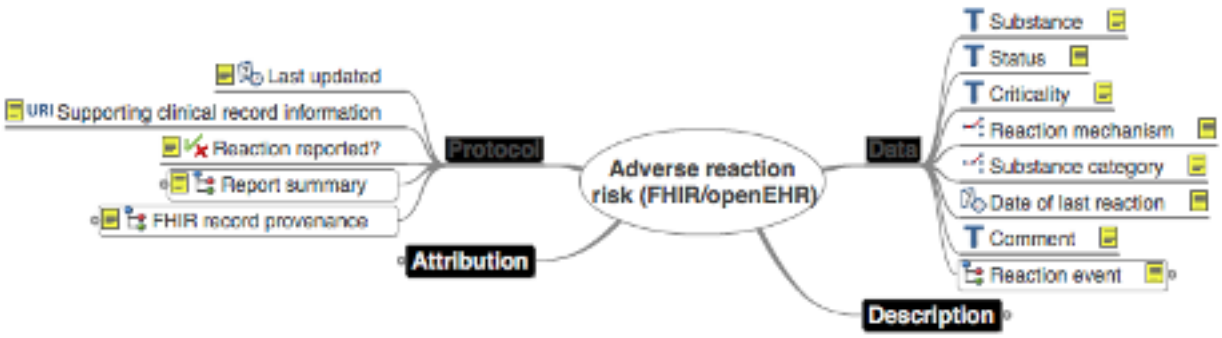
epSOSAllergennoDrugs

2.16.840.1.113883.6.96

Appendix G: Analysis of the openEHR information model

Status – the FHIR®/openEHR archetype for Adverse Reaction Risk is in its fourth review round as of November 2015.

http://www.openehr.org/ckm/ (search for Adverse Reaction Risk)



Data elements that could be encoded include:

- Substance
- Status
- Criticality
- Reaction mechanism
- Substance category
- Certainty
- Manifestation
- Severity of reaction

Purpose

- To record a clinical assessment of a propensity, or potential risk to an individual, of an adverse reaction upon future exposure to the specified substance, or class of substance
- Where a propensity is identified, to record information or evidence about reaction events that is characterized by any harmful or undesirable physiological response that is unique to the individual, and triggered by exposure of an individual to the identified substance or substance class.

Use

Use to provide a single place within the health record to document a range of clinical statements about adverse reactions, including:

- record a clinical assessment of the individual's propensity for a potential future reaction upon re-exposure; and
- record cumulative information about the reaction to each exposure
- Use to record information about the positive presence of the risk of an adverse reaction:
    - to support direct clinical care of an individual
    - as part of a managed adverse reaction or allergy/intolerance list
    - to support exchange of information about the propensity and events related to adverse reactions
    - to inform adverse reaction reporting; and
    - to assist computerized knowledge-based activities such as clinical decision support and alerts.

Use to record information about the risk of adverse reactions to a broad range of substances, including:

- incipients and excipients in medicinal preparations
- biological products
- metal salts
- organic chemical compounds

Adverse reaction may be:

- an immune mediated reaction - Types I-VI (including allergic reactions and hypersensitivities)
- a non-immune mediated reaction:
    - pseudo-allergic reactions
    - side effects
    - intolerances
    - drug toxicities

In clinical practice, distinguishing between immune-mediated and non-immune mediated reactions is difficult and often not practical. Identification of the type of reaction is not a proxy for seriousness or risk of harm to the patient, which is better expressed by the manifestation in clinical practice.

The risk of an adverse reaction event or manifestation should not be recorded without identifying a proposed causative substance or class of substance. If there is uncertainty that a specific substance is the cause, this uncertainty can be recorded using the 'Status' data element. If there are multiple possible substances that may have caused a reaction/manifestation, each substance should be recorded using a separate instance of this adverse reaction archetype/FHIR® resource with the 'Status' set to an initial state of 'Suspected' so that adverse reaction checking can be activated in clinical systems. Once the substance, agent or class is later proven not to be the cause for a given reaction then the 'Status' can be modified to 'Refuted'.

This archetype/FHIR® resource has been designed to allow recording of information about a specific substance (amoxicillin, oysters, or bee sting venom) or, alternatively, a class of substance (eg Penicillins)). If a class of substance is recorded then identification of the exact substance can be recorded on a per exposure basis.

The scope of this archetype/FHIR® resource has deliberately focused on identifying a pragmatic data set that are used in most clinical systems or will be suitable for most common clinical scenarios, however it permits extension of the model when additional detail is required, for example 'Reaction details', 'Exposure details', and 'Reporting details' slots. Examples of clinical situations where the extension may be required include: a detailed allergist/ immunologist assessment, for reporting to regulatory bodies or use in a clinical trial.

The act of recording any adverse reaction risk in a health record involves the clinical assessment that a potential hazard exists for an individual if they are exposed to the same substance/agent/class in the future – that is, a relative contraindication - and the default 'Criticality' value should be set to 'Low risk'. If a clinician considers that it is not safe for the individual to be deliberately re-exposed to the substance/agent again, for example, following a manifestation of a life-threatening anaphylaxis, then the 'Criticality' data element should be amended to 'High'.

A formal Adverse Event Report to regulatory bodies is a document that will contain a broad range of information in addition to the specific details about the adverse reaction. The report could utilize parts of this Risk of adverse reaction archetype/FHIR® resource plus include additional data as required per jurisdiction.

An adverse reaction or allergy/intolerance list is a record of all identified propensities for an adverse reaction for the individual upon future exposure to the substance or class, additionally providing potential access to the evidence provided by details about each reaction event, such as manifestation.

Valuable first-level information that could be presented to the clinician when they need to assess propensity for future reactions are:

- statements about previous clinical manifestations following exposure
- source of the information/reporter
- 'Criticality' flag.

Second-level information can be drawn from each exposure event and links to additional detailed information such as history, examination and diagnoses stored elsewhere in the record, if it is available.

Out of scope
The archetype is not to be used for recording physiological reactions to physical agents, such as heat, cold, sunlight, vibration, exercise activity, by infectious agents or food contaminants. Use archetypes/FHIR® resources for Problem/Diagnosis (openEHR) or Conditions (FHIR®).

Not to be used to record adverse events, including failures of clinical process, interventions or products. For example:

- abnormal use or mistakes/errors made in maladministration of an agent or substance
- incorrect dosage
- mislabeling
- harm or injury caused by an intervention or procedure
- overdose or poisoning

Not to be used to record an adverse reaction where the substance is unknown. Use EVALUATION.problem_diagnosis or CLUSTER.symptoms to record as part of the health record until a possible substance is identified.

Not to be used to record reactions to transfusions of blood products. Use a specific archetype for the purpose.

Not to be used as a proxy for an Adverse Event Report. See above for how it may be used as one component of an Adverse Event Report.

Not to be used for recording alerts.

Not to be used for recording failed therapy.

Not to be used for the explicit recording of an absence (or negative presence) of a reaction to 'any substances' or to identified substances, for example 'No known allergies or adverse reactions' or 'No known allergies to Penicillin'. Use the EVALUATION. exclusion-adverse_reaction archetype to express a positive statement of adverse reaction exclusion.

Not to be used for the explicit recording that no information could be obtained about the adverse reaction status of a patient. Use the EVALUATION.absence archetype to record that a positive statement that information could not be obtained, for example, if a non-cooperative patient refuses to answer questions.

Appendix H: Analysis of the US Federal Health Information Model

The Federal Health Information Model is a project under a larger program called Federal Health Interoperability Modeling and Standards (FHIMS), which is an initiative of the Federal Health Architecture (FHA). Briefly, the United States federal government has established a Federal Enterprise Architecture (FEA), which provides guidance to federal agencies on how they should develop their enterprise architectures. The methodology used by FEA, the Federal Segment Architecture Methodology (FSAM) recognizes that some "lines of businesses" in which the federal

government is engaged cross agency boundaries. The healthcare line of business is one such case. As a result, the FHA was established as a partnership of over 20 departments and agencies to coordinate Healthcare Information Technology (sometimes called Healthcare IT, or HIT) activities among those partners. The FHA is managed by the Office of the National Coordinator for Health IT (ONC). The FHA has served as a forum by which the partner agencies have collaborated on several important initiatives, including the Nationwide Health Information Network.

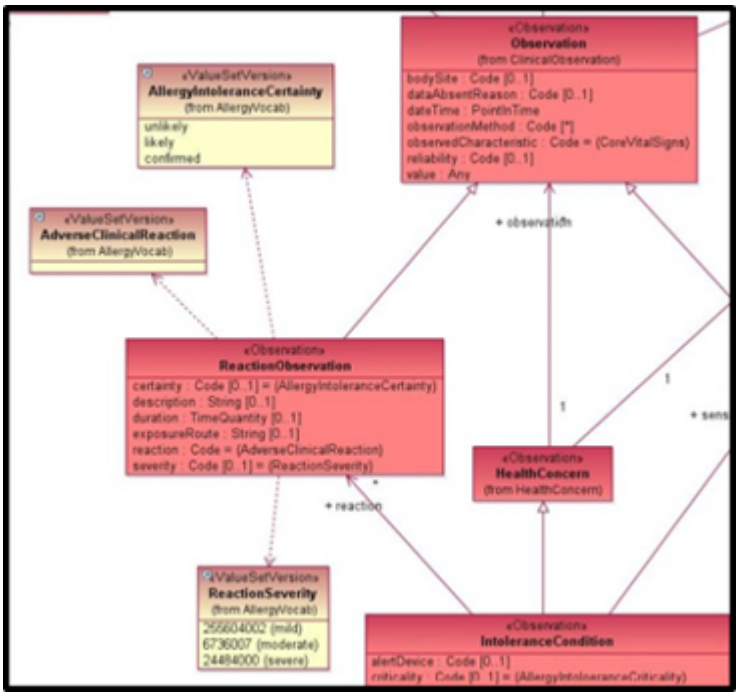
The FHIMS program is intended to coordinate the efforts of the partner agencies with respect to information and terminology standards, including the coordination of agency efforts at relevant Standards Development Organizations (SDOs) such as Health Level Seven (HL7®), the National Council for Prescription Drug Programs (NCPDP), Integrating the Healthcare Enterprise (IHE), and others.

Another FHIMS initiative is the Federal Health Terminology Model project, which coordinates partner agency efforts to develop healthcare terminology models, and to enumerate "value sets" that can be associated with the Information Model. The Terminology Model is closely related to the Information Model, as they are each describing the same real-world concepts from two different angles”[3].

The Federal Health Information Model is a UML construct defining classes of data with linked terminological value sets proposed as reference values for attributes in the model. There are two classes proposed which directly relate to documentation of the use cases from chapter 2. ReactionObservations model the data class describing report of a hypersensitivity reaction event as presented in use case 2.1.1. The IntoleranceConditions class, as elements of the IntoleranceConditionList, mirror the content of the Allergic Propensity List proposed in use case 2.1.2 to support drug alerting.

ReactionObservation class: is a specialization (subtype) of **Observation** and inherits the attributes from that class. “This class documents an Observation of an adverse physiological response attributed to the exposure of the Patient to the given substance. Note that the dates may be unspecified, such as when the Patient reports that she breaks out in hives when she eats peanuts[3].”

FHIM: ReactionObservation class



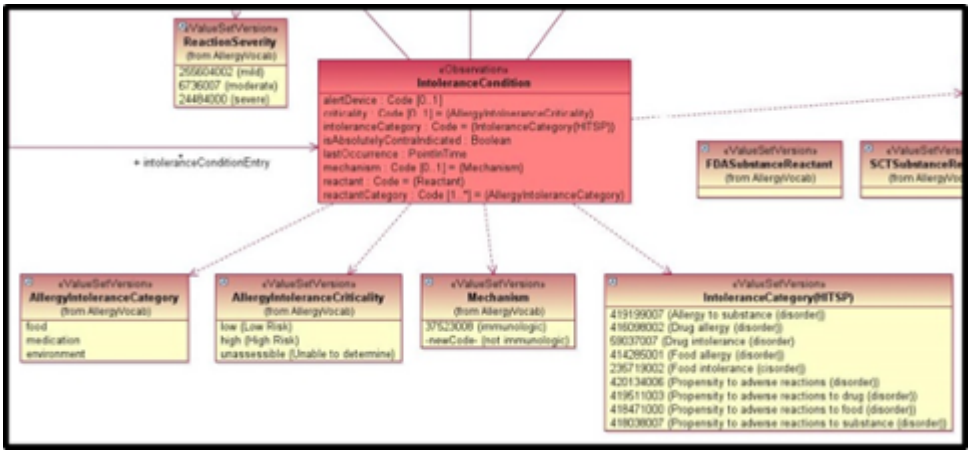
Coded attributes from this model which relate to use case 1: “Allergic reaction to hydrochlorothiazide consisting of hives” might be:

Attribute	Value

observedCharacteristic	NULL
bodySite	“skin”
observationMethod	
certainty	“likely”
exposureRoute	“ingested”
reaction	“Hives”
severity	6736007|Moderate|

IntoleranceCondition class: is a linked artifact to ReactionObservation and “Describes an observation of an ‘Intolerance Condition’ of the Patient. Intolerance Conditions are typically allergies, but the concept of an intolerance condition is broader than just allergies. For example, an adverse reaction such as the patient becomes nauseous after taking a particular antibiotic is not an allergy, but may serve as a contra-indicator to the use of that antibiotic. In general, Intolerance Conditions as caused by Food, Drugs, or some environmental factor such as mold, insect venom (i.e., bee stings), or pet dander”[3].

FHIM:IntoleranceCondition class and selected value sets



Coded attributes from this model which relate to use case 2.1.2: “Propensity for allergic reaction to hydrochlorothiazide with history of hives” might be:

Class attributes FHIM Intolerance Condition

Attribute	Value
criticality	“high (High risk)”
intoleranceCategory	419511003|Propensity to adverse reaction to drug(disorder)|
isAbsolutelyContraindicated	“No”
Mechanism	37523008 |Immunologic|
reactant	RxCUI 5487|Hydrochlorothiazide|
reactantCategory	“medication”

Appendix I: Inclusive Information Model

After considering reference information models from various standards development organizations and other national or regional sources, this inclusive information model was synthesized. The purpose of the model is to provide a conceptual framework to understand and align the various models but does not replace the individual models. (The details on each of the source information models are available in the appendixes)

Figure Appendix I:-1 illustrates the inclusive information model and shows the relationship between the three classes included in the model. The **Propensity** class is the centerpiece. A propensity class may be associated with zero-to-many **Adverse Reaction** classes and zero-to-many **Adverse Sensitivity Test Result** classes.

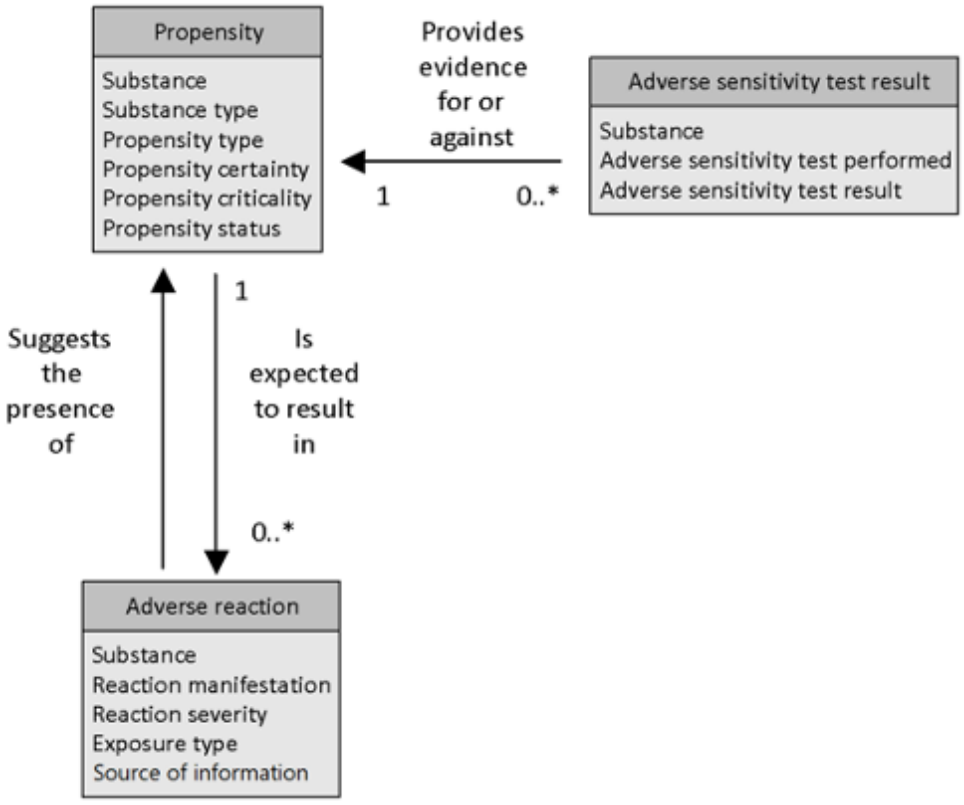


Figure Appendix I:-1: Inclusive information model for XXX. A conceptual framework to understand and align the various models.

The following tables depict the three classes and their data elements. Only data elements specific to the adverse sensitivity use case are shown. Generic data elements such as date, time, patient and provider identifiers are omitted.

Table Appendix I:-1: Overview of the propensity class and a description of the associated data elements

Data element	Description	Notes
Substance	Represents the specific allergen or other agent/ substance to which the patient has an adverse reaction propensity. A substance is a physical material which can mean a drug or biologic, food, chemical agent, plants, animals, plastics etc.	
Substance type	Represents the type of substance related to the propensity e.g. drug, food, environment, vaccine etc.	
Propensity type	Indicates whether the propensity is an allergy, non-allergic hypersensitivity or intolerance.	
Propensity certainty	Indicates whether there is evidence that the propensity has been confirmed. For example, an allergy could be further categorized as: Confirmed - via laboratory testing or witnessed observation or other strong evidence, or Suspected (Unconfirmed) - Patient reported but not further verified by clinical history, diagnostic testing or is uncertain.	
Propensity criticality	Indicates the potential seriousness of the propensity for a future reaction. This represents a clinical judgment about the worst-case scenario for a future reaction. It would be based on the severity of past reactions, the dose and route of exposure that produced past reactions, and the life threatening or organ system threatening potential of the reaction type. Criticality is an attribute of the propensity, not the reaction(s).	Not the same as severity of the reaction, because a severe reaction can be non-critical and vice versa. Assessing criticality may be difficult especially as the notion may be unfamiliar to those providers that are not allergy specialists and who may confuse this element with the severity of a previous or current reaction. For this reason, criticality should be documented with caution.
Propensity status	Indicates the current status of the propensity. For example, an allergy may become 'Resolved' after de-sensitization (see 6.2 for the discussion about allergy desensitization).	

Table Appendix I:-2: Overview of the adverse reaction class and a description of the associated data elements

Data element	Description	Notes
Substance	Represents the specific allergen or other agent/ substance to which the patient has an adverse reaction propensity. A substance is a physical material which can mean a drug or biologic, food, chemical agent, plants, animals, plastics etc.	
Reaction manifestation	Indicates the specific adverse reaction that occurred. Example: Rash, Hives	A negative entry (e.g., "no adverse reaction observed") can be used to document an exception to a propensity to a class of substance (e.g., patient has penicillin allergy but can tolerate amoxicillin)
Reaction severity	How severe the reaction was	
Exposure type (route)	How the exposure occurred. Example: oral, airborn, topical, etc.	
Source of information	How the observation was made e.g., patient reported, observed by family member, observed by healthcare professional	

Table Appendix I:-3: Overview of the adverse sensitivity class and a description of the associated data elements

Data element	Description	Notes
Substance	Represents the specific allergen or other agent/substance to which the patient has an adverse reaction propensity. A substance is a physical material which can mean a drug or biologic, food, chemical agent, plants, animals, plastics etc.	
Adverse sensitivity test performed	Represents the specific allergy test being performed ex: LOINC code 6206-7 Peanut IgE Ab [Units/volume] in Serum	
Adverse sensitivity test result	Represents the test result	

There were other published allergy and hypersensitivity information models being considered at the initial drafting of this document in 2014, which included epSOS, openEHR, US Federal Health Information Model and UK NHS Connecting for Health Information Model. Their analysis fed into the creation of the inclusive model. Since then, HL7®-related information models, especially FHIR®, have become increasingly popular. Therefore, this document focuses more on these models. The analyses of the other models can be found in the Appendix. Note that the information may not be up-to-date, and some of the projects which created the models may no longer be active (e.g. the epSOS project concluded in 2014).