CP.6.2 Immunization Management

Sparx Enterprise Architect Generated

Prototype Interoperability Specification



**EHR Interoperability Work Group**

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21 November 2013 Draft, Stephen Hufnagel PhD, Editor

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Model Documentation

## Nov 2013 Prototype CP.6.2 Immunization Management Interoperability Specification

Type: Package

Status: Proposed. Version 1.0. Phase 1.0.

Package: EHR-S FIM

Detail: *Created on 11/4/2013*. *Last modified on 11/20/2013*

GUID: {3E270C13-6A97-497b-95D3-AECCC53458BC}

### EHR-S FIM CP.6.2 Immunization Management

Type: Package

Status: Proposed. Version 1.0. Phase 1.0.

Package: Nov 2013 Prototype CP.6.2 Immunization Management Interoperability Specification

Detail: *Created on 11/4/2013*. *Last modified on 11/20/2013*

GUID: {C82345D5-6381-476d-A90E-0318A2BBF415}

**EHR-S FIM CP.6.2 Immunization Management** - *(Use Case diagram)*

Created By: Steve Hufnagel *on* 11/19/2013

Last Modified: 11/20/2013

Version: 1.0. *Locked:* False

GUID: {98775BCE-C2B3-4b5c-9B0E-60311534B1AF}

**Use-Case Description (Notional Scenario)**

1. A Clinician reviews the patient’s EMR for Allergies and Intolerances, reviews the Patient’s Immunization-Schedule, treats (immunizes) the Patient with a Vaccine and observes Adverse-Reactions.
2. The EHR-S Immunization related managers can

Capture, Auto-populate, Maintain, Render, Transmit, Exchange,

Harmonize, Update, or Determine

1. The following data-modules:

Immunization-Administrations, Allergies, Intolerances, Adverse-Events    Events, Schedules, Plans and Educational Materials

This diagram shows that

* Patient, Clinician and EHR-S interactions are through the EHR-S GUI
* Record Entries can be an order, treatment or observation; where, Record Entries  depend on the Clinician to observe the patient, write orders, treat the Patient or manage the EMR.
* Electronic Medical Record (EMR) management depends on the Patient, Clinician or their representatives to create, retrieve or update Patient data, according to scope-of-practice, organizational-policy, jurisdictional-law, patient preference-or-consent.
* Conformance Criteria (**CC**) bind Reference Model (RM) verbs (UML class operations) to RM nouns (UML classes or entities); where, applicable System operations on applicable System data are defined by CCs (e.g., CP.6.2 Immunization Management's CCs).
* RM Adjectives are defined as UML type (generalization element) to the core RM nouns (e.g., Observation, Order, Treatment or their descendents)
* Histories are defined as lists of Observations, Treatments or Orders of various types.
* Care Plans are defined as lists of Orders

CP.6.2 Conformance Criteria are:

1. The system SHALL provide the ability to capture, maintain and render immunization administration details as discrete data, including:(1) the immunization name/type, strength and dose;(2) date and time of administration;(3) manufacturer, lot number, expiration date,(4) route and site of administration;(5) administering provider;(6) observations, reactions and complications;(7) reason immunization not given and/or immunization related activity not performed; according to scope of practice, organizational policy and/or jurisdictional law."
2. The system MAY auto-populate the immunization administration record as a by-product of verification of administering provider, patient, medication, dose, route and time according to scope of practice, organizational policy and/or jurisdictional law.
3. The system SHALL provide the ability to determine and render required immunizations, and when they are due, based on widely accepted immunization schedules, when rendering encounter information.
4. The system SHOULD provide the ability to capture, in a discrete field, an allergy/adverse reaction to a specific immunization.
5. The system SHALL conform to function CP.3.2 (Manage Patient Clinical Measurements) to capture other clinical data pertinent to the immunization administration (e.g., vital signs).
6. The system SHOULD provide the ability to link standard codes (e.g. NDC, LOINC, SNOMED or CPT) with discrete data elements associated with an immunization.
7. The system SHALL provide the ability to maintain the immunization schedule.
8. The system SHALL provide the ability to render a patient‘s immunization history upon request for appropriate authorities such as schools or day-care centers.
9. The system SHALL conform to function CP.1.2 (Manage Allergy, Intolerance and Adverse Reaction List).
10. The system SHOULD transmit required immunization administration information to a public health immunization registry according to scope of practice, organizational policy and/or jurisdictional law.
11. The system SHOULD exchange immunization histories with public health immunization registries according to scope of practice, organizational policy and/or jurisdictional law.
12. The system SHOULD harmonize Immunization histories with a public health immunization registry according to scope of practice, organizational policy and/or jurisdictional law.
13. The system SHOULD capture and render immunization histories from a public health immunization registry.
14. The system SHALL conform to function CP.1.6 (Manage Immunization List).
15. The system SHOULD provide the ability to update immunization histories at the time of capturing an immunization administration.
16. The system SHALL provide the ability to render the immunization order as written (i.e., exact clinician order language) when rendering administration information.
17. "The system SHALL provide the ability to determine due and overdue ordered immunizations and render a notification. "
18. The system SHALL provide the ability to render a patient educational information regarding the administration (e.g., Vaccine Information Statement (VIS)).
19. The system SHALL provide the ability to capture that patient educational information (e.g., VIS) was provided at the time of immunization administration.
20. The system SHALL provide the ability to capture documentation that patient educational information (e.g., VIS) was provided at the time of immunization administration.
21. The system SHALL provide the ability to capture the receiving entity (e.g., patient, representative, organization) when patient education information is provided at the time of immunization administration.
22. The system SHOULD provide the ability to capture and maintain immunization refusal reasons as discrete data.
23. The system SHOULD provide the ability to capture patient preferences regarding receipt of immunization (e.g. refusal of certain vaccine types) at time of immunization administration.



Figure: 1

**EHR-S FIM CP.6.2 Immunization Management (Conceptual Model)** - *(Class diagram)*

Created By: Steve Hufnagel *on* 11/3/2013

Last Modified: 11/20/2013

Version: Prototype. *Locked:* False

GUID: {DBFC03AF-5FB8-463d-B1D0-6AA4763D3580}

This diagram shows that

* Record Entries can be an order, treatment or observation
* RM Adjectives are defined as UML type (generalization element) to the core RM nouns (e.g., Observation, Order, Treatment or their descendents)
* Histories are defined as lists of Observations, Treatments or Orders of various types.
* Care Plans are defined as lists of Orders
* Record Entries can be associated / linked as Observations, Treatments or Orders; where, they may be linked into an encounter which also has a Provider and possible also a patient signature
* An Electronic Medical Record (EMR) is a set of Patient Care Data, organized into lists.



Figure: 2

**EHR-S FIM CP.6.2 Immunization Management (Conceptual Traceability Model)** - *(Class diagram)*

Created By: Protege User *on* 11/3/2013

Last Modified: 11/20/2013

Version: 1.0. *Locked:* False

GUID: {65E55CA5-6194-49fb-8540-8317305F1F12}

This diagram shows how Conformance Criteria can be linked to classes



Figure: 3

**EHR-S FIM CP.6.2 Immunization Management (Logical Model)** - *(Class diagram)*

Created By: Protege User *on* 10/31/2013

Last Modified: 11/20/2013

Version: 1.0. *Locked:* False

GUID: {AC7FD82B-A023-4f71-A34D-E1011E83E331}

This diagram shows how Conformance Criteria can be linked to particular class operations and/or operations.



Figure: 4

**EHR-S FIM CP.6.2 Immunization Management (Logical Model-2)** - *(Class diagram)*

Created By: Protege User *on* 11/4/2013

Last Modified: 11/20/2013

Version: 1.0. *Locked:* False

GUID: {8E95DBDF-5ED1-44bc-9C28-D0C30F45F010}

This diagram shows how Conformance Criteria can be linked to particular class operations and/or operations.



Figure: 5

#### CP.3.2 (Manage Patient Clinical Measurements)

Type: **Actor**

Status: Proposed. Version 1.0. Phase 1.0.

Package: EHR-S FIM CP.6.2 Immunization Management Keywords:

Detail: *Created on* *11/19/2013*. *Last modified on 11/19/2013*.

GUID: {EA24C80A-8F77-4793-B3B8-0A41E7905F52}

#### Clinician

Type: **Actor**

Status: Proposed. Version 1.0. Phase 1.0.

Package: EHR-S FIM CP.6.2 Immunization Management Keywords:

Detail: *Created on* *11/19/2013*. *Last modified on 11/19/2013*.

GUID: {95E51E2C-2802-428a-B052-5FD1F2A841B0}

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| UseCaseLink  Source -> Destination | Public  Clinician | Public  treat Patient |  |
| UseCaseLink  Source -> Destination | Public  Clinician | Public  observe Patient |  |
| UseCaseLink  Source -> Destination | Public  Clinician | Public  Interact with GUI |  |
| UseCaseLink  Source -> Destination | Public  manage EMR | Public  Clinician |  |
| UseCaseLink  Source -> Destination | Public  Clinician | Public  write Orders |  |
| Dependency dependency  Source -> Destination | Public  Clinician | Public  Patient |  |

#### EHR System

Type: **Actor**

Status: Proposed. Version 1.0. Phase 1.0.

Package: EHR-S FIM CP.6.2 Immunization Management Keywords:

Detail: *Created on* *11/19/2013*. *Last modified on 11/20/2013*.

GUID: {643A5F18-2BFB-43f4-9898-716EB4499A29}

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| UseCaseLink  Source -> Destination | Public  EHR System | Public  auto-populate the immunization administration record |  |
| UseCaseLink  Source -> Destination | Public  EHR System | Public  determine and render required immunizations, and when they are due |  |
| UseCaseLink  Source -> Destination | Public  EHR System | Public  capture, in a discrete field, an allergy/adverse reaction to a specific immunization |  |
| UseCaseLink  Source -> Destination | Public  EHR System | Public  conform to function CP.3.2 (Manage Patient Clinical Measurements) |  |
| UseCaseLink  Source -> Destination | Public  EHR System | Public  link standard codes |  |
| UseCaseLink  Source -> Destination | Public  EHR System | Public  maintain the immunization schedule |  |
| UseCaseLink  Source -> Destination | Public  render | Public  EHR System |  |
| UseCaseLink  Source -> Destination | Public  EHR System | Public  conform |  |
| UseCaseLink  Source -> Destination | Public  EHR System | Public  transmit |  |
| UseCaseLink  Source -> Destination | Public  Interact with GUI | Public  EHR System |  |

#### Patient

Type: **Actor**

Status: Proposed. Version 1.0. Phase 1.0.

Package: EHR-S FIM CP.6.2 Immunization Management Keywords:

Detail: *Created on* *11/20/2013*. *Last modified on 11/20/2013*.

GUID: {CCCA7BB7-53AB-41ad-88E8-91ACC56DF511}

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| UseCaseLink  Source -> Destination | Public  Patient | Public  manage EMR |  |
| Dependency dependency  Source -> Destination | Public  Clinician | Public  Patient |  |

#### Interact with GUI

Type: **UseCase**

Status: Proposed. Version 1.0. Phase 1.0.

Package: EHR-S FIM CP.6.2 Immunization Management Keywords:

Detail: *Created on* *11/19/2013*. *Last modified on 11/19/2013*.

GUID: {F309B9C8-EFBB-40b0-A0ED-A0A4F67AEE8E}

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| UseCaseLink  Source -> Destination | Public  Clinician | Public  Interact with GUI |  |
| UseCaseLink  Source -> Destination | Public  Interact with GUI | Public  EHR System |  |

#### auto-populate the immunization administration record

Type: **UseCase**

Status: Proposed. Version 1.0. Phase 1.0.

Package: EHR-S FIM CP.6.2 Immunization Management Keywords:

Detail: *Created on* *11/19/2013*. *Last modified on 11/19/2013*.

GUID: {06CAB4A3-2C82-4cc8-A758-6B1C02774961}

| Responsibilities (external requirements) | |
| --- | --- |
|  | CP.6.2#02 The system MAY auto-populate the immunization administration record as a by-product of verification of administering provider, patient, medication, dose, route and time according to scope of practice, organizational policy and/or jurisdictiona *(Proposed, Medium difficulty)*  needs clarification  jurisdictiona misspelled |

| Constraints | |
| --- | --- |
|  | verification of administering provider, patient, medication, dose, route: *(Pre-condition, Status is Approved*) |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| UseCaseLink  Source -> Destination | Public  EHR System | Public  auto-populate the immunization administration record |  |
| Realization  Source -> Destination | Public  auto-populate the immunization administration record | Public  CP.6.2#02 The system MAY auto-populate the immunization administration record as a by-product of verification of administering provider, patient, medication, dose, route and time according to scope of practice, organizational policy and/or jurisdictiona |  |

#### capture, in a discrete field, an allergy/adverse reaction to a specific immunization

Type: **UseCase**

Status: Proposed. Version 1.0. Phase 1.0.

Package: EHR-S FIM CP.6.2 Immunization Management Keywords:

Detail: *Created on* *11/19/2013*. *Last modified on 11/19/2013*.

GUID: {B536B1F4-CE98-457b-8B54-7755078DD249}

| Responsibilities (external requirements) | |
| --- | --- |
|  | CP.6.2#01 The system SHALL provide the ability to capture, maintain and render immunization administration details as discrete data, including:(1) the immunization name/type, strength and dose;(2) date and time of administration;(3) manufacturer, lot numb *(Proposed, Medium difficulty)* |
|  | CP.6.2#04 The system SHOULD provide the ability to capture, in a discrete field, an allergy/adverse reaction to a specific unization. *(Proposed, Medium difficulty)*  IS: CP.6.2#04 The system SHOULD provide the ability to capture, in a discrete field, an allergy/adverse reaction to a specific **imm**unization.  SB: CP.6.2#04 The system SHOULD provide the ability to capture, in a discrete field, an allergy/adverse reaction to a specific **im**munization. |
|  | CP.6.2#13 The system SHOULD capture and render immunization histories from a public health immunization registry. *(Proposed, Medium difficulty)* |

| Constraints | |
| --- | --- |
|  | an allergy/adverse reaction to a specific immunization: *(Pre-condition, Status is Approved*) |
|  | capture, in a discrete field: *(Post-condition, Status is Approved*) |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| UseCaseLink  Source -> Destination | Public  EHR System | Public  capture, in a discrete field, an allergy/adverse reaction to a specific immunization |  |
| Realization  Source -> Destination | Public  capture, in a discrete field, an allergy/adverse reaction to a specific immunization | Public  CP.6.2#04 The system SHOULD provide the ability to capture, in a discrete field, an allergy/adverse reaction to a specific unization. |  |
| Realization  Source -> Destination | Public  capture, in a discrete field, an allergy/adverse reaction to a specific immunization | Public  CP.6.2#13 The system SHOULD capture and render immunization histories from a public health immunization registry. |  |
| Realization  Source -> Destination | Public  capture, in a discrete field, an allergy/adverse reaction to a specific immunization | Public  CP.6.2#01 The system SHALL provide the ability to capture, maintain and render immunization administration details as discrete data, including:(1) the immunization name/type, strength and dose;(2) date and time of administration;(3) manufacturer, lot numb |  |

#### conform

Type: **UseCase**

Status: Proposed. Version 1.0. Phase 1.0.

Package: EHR-S FIM CP.6.2 Immunization Management Keywords:

Detail: *Created on* *11/19/2013*. *Last modified on 11/19/2013*.

GUID: {5015D41C-8CED-4597-AC30-9D82C42DE81D}

| Responsibilities (external requirements) | |
| --- | --- |
|  | CP.6.2#14 The system SHALL conform to function CP.1.6 (Manage Immunization List). *(Proposed, Medium difficulty)* |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| UseCaseLink  Source -> Destination | Public  EHR System | Public  conform |  |
| Realization  Source -> Destination | Public  conform | Public  CP.6.2#14 The system SHALL conform to function CP.1.6 (Manage Immunization List). |  |

#### conform to function CP.3.2 (Manage Patient Clinical Measurements)

Type: **UseCase**

Status: Proposed. Version 1.0. Phase 1.0.

Package: EHR-S FIM CP.6.2 Immunization Management Keywords:

Detail: *Created on* *11/19/2013*. *Last modified on 11/19/2013*.

GUID: {6B0A54B4-CD00-418a-9C93-7D0480105FE8}

| Responsibilities (external requirements) | |
| --- | --- |
|  | CP.6.2#05 The system SHALL conform to function CP.3.2 (Manage Patient Clinical Measurements) to capture other clinical data pertinent to the immunization administration (e.g., vital signs). *(Proposed, Medium difficulty)* |
|  | CP.6.2#09 The system SHALL conform to function CP.1.2 (Manage Allergy, Intolerance and Adverse Reaction List). *(Proposed, Medium difficulty)* |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| UseCaseLink  Source -> Destination | Public  EHR System | Public  conform to function CP.3.2 (Manage Patient Clinical Measurements) |  |
| Realization  Source -> Destination | Public  conform to function CP.3.2 (Manage Patient Clinical Measurements) | Public  CP.6.2#05 The system SHALL conform to function CP.3.2 (Manage Patient Clinical Measurements) to capture other clinical data pertinent to the immunization administration (e.g., vital signs). |  |
| Realization  Source -> Destination | Public  conform to function CP.3.2 (Manage Patient Clinical Measurements) | Public  CP.6.2#09 The system SHALL conform to function CP.1.2 (Manage Allergy, Intolerance and Adverse Reaction List). |  |

#### determine and render required immunizations, and when they are due

Type: **UseCase**

Status: Proposed. Version 1.0. Phase 1.0.

Package: EHR-S FIM CP.6.2 Immunization Management Keywords:

Detail: *Created on* *11/19/2013*. *Last modified on 11/19/2013*.

GUID: {ED7F809D-3871-43cf-8C10-4085A76D72E9}

| Responsibilities (external requirements) | |
| --- | --- |
|  | CP.6.2#03 The system SHALL provide the ability to determine and render required immunizations, and when they are due, based on widely accepted immunization schedules, when rendering encounter information. *(Proposed, Medium difficulty)* |

| Constraints | |
| --- | --- |
|  | required immunizations: *(Pre-condition, Status is Approved*) |
|  | due-date: *(Post-condition, Status is Approved*) |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| Realization  Source -> Destination | Public  determine and render required immunizations, and when they are due | Public  CP.6.2#03 The system SHALL provide the ability to determine and render required immunizations, and when they are due, based on widely accepted immunization schedules, when rendering encounter information. |  |
| UseCaseLink  Source -> Destination | Public  EHR System | Public  determine and render required immunizations, and when they are due |  |

#### link standard codes

Type: **UseCase**

Status: Proposed. Version 1.0. Phase 1.0.

Package: EHR-S FIM CP.6.2 Immunization Management Keywords:

Detail: *Created on* *11/19/2013*. *Last modified on 11/19/2013*.

GUID: {A5EE372A-5627-41a1-AAFE-97A1B60AF75A}

| Responsibilities (external requirements) | |
| --- | --- |
|  | CP.6.2#06 The system SHOULD provide the ability to link standard codes (e.g. NDC, LOINC, SNOMED or CPT) with discrete data elements associated with an immunization. *(Proposed, Medium difficulty)* |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| UseCaseLink  Source -> Destination | Public  EHR System | Public  link standard codes |  |
| Realization  Source -> Destination | Public  link standard codes | Public  CP.6.2#06 The system SHOULD provide the ability to link standard codes (e.g. NDC, LOINC, SNOMED or CPT) with discrete data elements associated with an immunization. |  |

#### maintain the immunization schedule

Type: **UseCase**

Status: Proposed. Version 1.0. Phase 1.0.

Package: EHR-S FIM CP.6.2 Immunization Management Keywords:

Detail: *Created on* *11/19/2013*. *Last modified on 11/19/2013*.

GUID: {6DC9F34E-A81B-49bd-AA12-042D4E89D5D5}

| Responsibilities (external requirements) | |
| --- | --- |
|  | CP.6.2#01 The system SHALL provide the ability to capture, maintain and render immunization administration details as discrete data, including:(1) the immunization name/type, strength and dose;(2) date and time of administration;(3) manufacturer, lot numb *(Proposed, Medium difficulty)* |
|  | CP.6.2#07 The system SHALL provide the ability to maintain the immunization schedule. *(Proposed, Medium difficulty)* |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| Realization  Source -> Destination | Public  maintain the immunization schedule | Public  CP.6.2#07 The system SHALL provide the ability to maintain the immunization schedule. |  |
| UseCaseLink  Source -> Destination | Public  EHR System | Public  maintain the immunization schedule |  |
| Realization  Source -> Destination | Public  maintain the immunization schedule | Public  CP.6.2#01 The system SHALL provide the ability to capture, maintain and render immunization administration details as discrete data, including:(1) the immunization name/type, strength and dose;(2) date and time of administration;(3) manufacturer, lot numb |  |

#### manage EMR

Type: **UseCase**

Status: Proposed. Version 1.0. Phase 1.0.

Package: EHR-S FIM CP.6.2 Immunization Management Keywords:

Detail: *Created on* *11/20/2013*. *Last modified on 11/20/2013*.

GUID: {9CC0EBAE-E293-455e-9911-2FD71C0A94F3}

| Scenarios | |
| --- | --- |
|  | Basic Path - Basic Path  *Notes* |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| UseCaseLink  Source -> Destination | Public  manage EMR | Public  Clinician |  |
| Dependency  Source -> Destination | Public  Record Entry | Public  manage EMR |  |
| Dependency  Source -> Destination | Public  manage EMR | Public  EMR |  |
| UseCaseLink  Source -> Destination | Public  Patient | Public  manage EMR |  |

#### observe

Type: **UseCase**

Status: Proposed. Version 1.0. Phase 1.0.

Package: EHR-S FIM CP.6.2 Immunization Management Keywords:

Detail: *Created on* *11/19/2013*. *Last modified on 11/19/2013*.

GUID: {6A6FEEC1-8C20-4461-8443-27514590DF14}

| Constraints | |
| --- | --- |
|  | adverse-reaction: *(Pre-condition, Status is Approved*) |

#### observe Patient

Type: **UseCase**

Status: Proposed. Version 1.0. Phase 1.0.

Package: EHR-S FIM CP.6.2 Immunization Management Keywords:

Detail: *Created on* *11/19/2013*. *Last modified on 11/20/2013*.

GUID: {C5329FE8-1FB9-4543-80D4-57A1337BE44C}

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| UseCaseLink  Source -> Destination | Public  Clinician | Public  observe Patient |  |
| Dependency dependency  Source -> Destination | Public  Record Entry | Public  observe Patient |  |

#### render

Type: **UseCase**

Status: Proposed. Version 1.0. Phase 1.0.

Package: EHR-S FIM CP.6.2 Immunization Management Keywords:

Detail: *Created on* *11/19/2013*. *Last modified on 11/19/2013*.

GUID: {3CCE0752-5739-4929-BC31-C73844A47F91}

| Responsibilities (external requirements) | |
| --- | --- |
|  | CP.6.2#01 The system SHALL provide the ability to capture, maintain and render immunization administration details as discrete data, including:(1) the immunization name/type, strength and dose;(2) date and time of administration;(3) manufacturer, lot numb *(Proposed, Medium difficulty)* |
|  | CP.6.2#08 The system SHALL provide the ability to render a patient‘s immunization history upon request for appropriate authorities such as schools or day-care centers. *(Proposed, Medium difficulty)* |
|  | CP.6.2#13 The system SHOULD capture and render immunization histories from a public health immunization registry. *(Proposed, Medium difficulty)* |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| Realization  Source -> Destination | Public  render | Public  CP.6.2#08 The system SHALL provide the ability to render a patient‘s immunization history upon request for appropriate authorities such as schools or day-care centers. |  |
| UseCaseLink  Source -> Destination | Public  render | Public  EHR System |  |
| Realization  Source -> Destination | Public  render | Public  CP.6.2#13 The system SHOULD capture and render immunization histories from a public health immunization registry. |  |
| Realization  Source -> Destination | Public  render | Public  CP.6.2#01 The system SHALL provide the ability to capture, maintain and render immunization administration details as discrete data, including:(1) the immunization name/type, strength and dose;(2) date and time of administration;(3) manufacturer, lot numb |  |

#### transmit

Type: **UseCase**

Status: Proposed. Version 1.0. Phase 1.0.

Package: EHR-S FIM CP.6.2 Immunization Management Keywords:

Detail: *Created on* *11/19/2013*. *Last modified on 11/19/2013*.

GUID: {9CB9133D-7985-4d6b-8829-D1012CC411A5}

| Responsibilities (external requirements) | |
| --- | --- |
|  | CP.6.2#10 The system SHOULD transmit required immunization administration information to a public health immunization registry according to scope of practice, organizational policy and/or jurisdictional law. *(Proposed, Medium difficulty)* |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| Realization  Source -> Destination | Public  transmit | Public  CP.6.2#10 The system SHOULD transmit required immunization administration information to a public health immunization registry according to scope of practice, organizational policy and/or jurisdictional law. |  |
| UseCaseLink  Source -> Destination | Public  EHR System | Public  transmit |  |

#### treat Patient

Type: **UseCase**

Status: Proposed. Version 1.0. Phase 1.0.

Package: EHR-S FIM CP.6.2 Immunization Management Keywords:

Detail: *Created on* *11/19/2013*. *Last modified on 11/20/2013*.

GUID: {0939F316-AF7E-4b93-8E9E-196F137105E1}

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| UseCaseLink  Source -> Destination | Public  Clinician | Public  treat Patient |  |
| Dependency  Source -> Destination | Public  Record Entry | Public  treat Patient |  |

#### write Orders

Type: **UseCase**

Status: Proposed. Version 1.0. Phase 1.0.

Package: EHR-S FIM CP.6.2 Immunization Management Keywords:

Detail: *Created on* *11/20/2013*. *Last modified on 11/20/2013*.

GUID: {15DBB19A-1DAD-4a26-94C9-A5643106D9D4}

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| UseCaseLink  Source -> Destination | Public  Clinician | Public  write Orders |  |
| Dependency  Source -> Destination | Public  Record Entry | Public  write Orders |  |

#### Immunization Administration Record

Type: **Class** Medication Administration

Status: Proposed. Version 1.0. Phase 1.0.

Package: EHR-S FIM CP.6.2 Immunization Management Keywords:

Detail: *Created on* *1/10/2012*. *Last modified on 11/20/2013*.

GUID: {1F6DA8BF-E7A1-4c33-AE1E-CAB1CDFEEE7B}

[FHIR Immunization](http://www.hl7.org/implement/standards/fhir/immunization.html): http://www.hl7.org/implement/standards/fhir/immunization.html

| Responsibilities (external requirements) | |
| --- | --- |
|  | CP.1.6#02 The system SHALL provide the ability to manage, as discrete data elements, data associated with any immunization given including date and time of administration, immunization type and series, lot number and manufacturer, dose and administration *(Proposed, Medium difficulty)* |
|  | CP.1.6#02 The system SHALL provide the ability to manage, as discrete data elements, data associated with any immunization given including date and time of administration, immunization type and series, lot number and manufacturer, dose and administration *(Proposed, Medium difficulty)* |
|  | CP.1.6#03 The system SHALL provide the ability to manage, as discrete elements, data associated with any immunization withheld (including date and time, immunization type, series, exception reason and immunization-withholding provider). *(Proposed, Medium difficulty)* |
|  | CP.1.6#05 The system SHALL provide the ability to capture the currently recommended date for an immunization booster dose with each immunization, if needed. *(Proposed, Medium difficulty)* |
|  | CP.6.2#01 The system SHALL provide the ability to capture, maintain and render immunization administration details as discrete data, including:(1) the immunization name/type, strength and dose;(2) date and time of administration;(3) manufacturer, lot numb *(Proposed, Medium difficulty)* |
|  | CP.6.2#01 The system SHALL provide the ability to capture, maintain and render immunization administration details as discrete data, including:(1) the immunization name/type, strength and dose;(2) date and time of administration;(3) manufacturer, lot numb *(Proposed, Medium difficulty)* |
|  | CP.6.2#01 The system SHALL provide the ability to capture, maintain and render immunization administration details as discrete data, including:(1) the immunization name/type, strength and dose;(2) date and time of administration;(3) manufacturer, lot numb *(Proposed, Medium difficulty)* |
|  | CP.6.2#02 The system MAY auto-populate the immunization administration record as a by-product of verification of administering provider, patient, medication, dose, route and time according to scope of practice, organizational policy and/or jurisdictiona *(Proposed, Medium difficulty)*  needs clarification  jurisdictiona misspelled |
|  | CP.6.2#04 The system SHOULD provide the ability to capture, in a discrete field, an allergy/adverse reaction to a specific unization. *(Proposed, Medium difficulty)*  IS: CP.6.2#04 The system SHOULD provide the ability to capture, in a discrete field, an allergy/adverse reaction to a specific **imm**unization.  SB: CP.6.2#04 The system SHOULD provide the ability to capture, in a discrete field, an allergy/adverse reaction to a specific **im**munization. |
|  | CP.6.2#05 The system SHALL conform to function CP.3.2 (Manage Patient Clinical Measurements) to capture other clinical data pertinent to the immunization administration (e.g., vital signs). *(Proposed, Medium difficulty)* |
|  | CP.6.2#06 The system SHOULD provide the ability to link standard codes (e.g. NDC, LOINC, SNOMED or CPT) with discrete data elements associated with an immunization. *(Proposed, Medium difficulty)* |
|  | CP.6.2#10 The system SHOULD transmit required immunization administration information to a public health immunization registry according to scope of practice, organizational policy and/or jurisdictional law. *(Proposed, Medium difficulty)* |
|  | CP.6.2#16 The system SHALL provide the ability to render the immunization order as written (i.e., exact clinician order language) when rendering administration information. *(Proposed, Medium difficulty)* |
|  | CP.6.2#16 The system SHALL provide the ability to render the immunization order as written (i.e., exact clinician order language) when rendering administration information. *(Proposed, Medium difficulty)* |
|  | CP.6.2#17 The system SHALL provide the ability to determine due and overdue ordered immunizations and render a notification. *(Proposed, Medium difficulty)* |
|  | CP.6.2#18 The system SHALL provide the ability to render a patient educational information regarding the administration (e.g., Vaccine Information Statement (VIS)). *(Proposed, Medium difficulty)* |
|  | CP.6.2#18 The system SHALL provide the ability to render a patient educational information regarding the administration (e.g., Vaccine Information Statement (VIS)). *(Proposed, Medium difficulty)* |
|  | CP.6.2#19 The system SHALL provide the ability to capture that patient educational information (e.g., VIS) was provided at the time of immunization administration. *(Proposed, Medium difficulty)* |
|  | CP.6.2#19 The system SHALL provide the ability to capture that patient educational information (e.g., VIS) was provided at the time of immunization administration. *(Proposed, Medium difficulty)* |
|  | CP.6.2#20 The system SHALL provide the ability to capture documentation that patient educational information (e.g., VIS) was provided at the time of immunization administration. *(Proposed, Medium difficulty)* |
|  | CP.6.2#20 The system SHALL provide the ability to capture documentation that patient educational information (e.g., VIS) was provided at the time of immunization administration. *(Proposed, Medium difficulty)* |
|  | CP.6.2#21 The system SHALL provide the ability to capture the receiving entity (e.g., patient, representative, organization) when patient education information is provided at the time of immunization administration. *(Proposed, Medium difficulty)* |
|  | CP.6.2#21 The system SHALL provide the ability to capture the receiving entity (e.g., patient, representative, organization) when patient education information is provided at the time of immunization administration. *(Proposed, Medium difficulty)* |
|  | CP.6.2#22 The system SHOULD provide the ability to capture and maintain immunization refusal reasons as discrete data. *(Proposed, Medium difficulty)* |
|  | CP.6.2#23 The system SHOULD provide the ability to capture patient preferences regarding receipt of immunization (e.g. refusal of certain vaccine types) at time of immunization administration. *(Proposed, Medium difficulty)* |
|  | CP.6.2#23 The system SHOULD provide the ability to capture patient preferences regarding receipt of immunization (e.g. refusal of certain vaccine types) at time of immunization administration. *(Proposed, Medium difficulty)* |

| Custom Properties | |
| --- | --- |
|  | isActive = False |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| NoteLink  Source -> Destination | Public  Immunization Administration Record | Public  <anonymous> |  |
| Association  Unspecified | Public  Immunization Future Booster | Public  Immunization Administration Record |  |
| Association  Unspecified | Public  health care organisation | Public  Immunization Administration Record |  |
| Realization  Source -> Destination | Public  Immunization Administration Record | Public  CP.1.6#02 The system SHALL provide the ability to manage, as discrete data elements, data associated with any immunization given including date and time of administration, immunization type and series, lot number and manufacturer, dose and administration |  |
| Realization  Source -> Destination | Public  Immunization Administration Record | Public  CP.6.2#02 The system MAY auto-populate the immunization administration record as a by-product of verification of administering provider, patient, medication, dose, route and time according to scope of practice, organizational policy and/or jurisdictiona |  |
| Realization  Source -> Destination | Public  Immunization Administration Record | Public  CP.1.6#03 The system SHALL provide the ability to manage, as discrete elements, data associated with any immunization withheld (including date and time, immunization type, series, exception reason and immunization-withholding provider). |  |
| Realization  Source -> Destination | Public  Immunization Administration Record | Public  CP.6.2#06 The system SHOULD provide the ability to link standard codes (e.g. NDC, LOINC, SNOMED or CPT) with discrete data elements associated with an immunization. |  |
| Realization  Source -> Destination | Public  Immunization Administration Record | Public  CP.6.2#05 The system SHALL conform to function CP.3.2 (Manage Patient Clinical Measurements) to capture other clinical data pertinent to the immunization administration (e.g., vital signs). |  |
| Realization  Source -> Destination | Public  Immunization Administration Record | Public  CP.6.2#20 The system SHALL provide the ability to capture documentation that patient educational information (e.g., VIS) was provided at the time of immunization administration. |  |
| Realization  Source -> Destination | Public  Immunization Administration Record | Public  CP.6.2#10 The system SHOULD transmit required immunization administration information to a public health immunization registry according to scope of practice, organizational policy and/or jurisdictional law. |  |
| Realization  Source -> Destination | Public  Immunization Administration Record | Public  CP.1.6#05 The system SHALL provide the ability to capture the currently recommended date for an immunization booster dose with each immunization, if needed. |  |
| Realization  Source -> Destination | Public  Immunization Administration Record | Public  CP.6.2#01 The system SHALL provide the ability to capture, maintain and render immunization administration details as discrete data, including:(1) the immunization name/type, strength and dose;(2) date and time of administration;(3) manufacturer, lot numb |  |
| Generalization  Source -> Destination | Public  Immunization Administration Record | Public  Medication Administration |  |
| Realization  Source -> Destination | Public  Immunization Administration Record | Public  CP.6.2#04 The system SHOULD provide the ability to capture, in a discrete field, an allergy/adverse reaction to a specific unization. |  |
| Realization  Source -> Destination | Public  Immunization Administration Record | Public  CP.6.2 Manage Immunization Administration |  |
| Realization  Source -> Destination | Public  Immunization Administration Record | Public  CP.1.6#02 The system SHALL provide the ability to manage, as discrete data elements, data associated with any immunization given including date and time of administration, immunization type and series, lot number and manufacturer, dose and administration |  |
| Realization  Source -> Destination | Public  Immunization Administration Record | Public  CP.6.2#01 The system SHALL provide the ability to capture, maintain and render immunization administration details as discrete data, including:(1) the immunization name/type, strength and dose;(2) date and time of administration;(3) manufacturer, lot numb |  |
| Realization  Source -> Destination | Public  Immunization Administration Record | Public  CP.6.2#01 The system SHALL provide the ability to capture, maintain and render immunization administration details as discrete data, including:(1) the immunization name/type, strength and dose;(2) date and time of administration;(3) manufacturer, lot numb |  |
| Generalization is-a  Source -> Destination | Public  Immunization Witheld Event | Public  Immunization Administration Record |  |
| Realization SHALL  Source -> Destination | Public  Immunization Administration Record | Public  CP.6.2#19 The system SHALL provide the ability to capture that patient educational information (e.g., VIS) was provided at the time of immunization administration. |  |
| Realization SHALL  Source -> Destination | Public  Immunization Administration Record | Public  CP.6.2#18 The system SHALL provide the ability to render a patient educational information regarding the administration (e.g., Vaccine Information Statement (VIS)). |  |
| Realization SHALL  Source -> Destination | Public  Immunization Administration Record | Public  CP.6.2#17 The system SHALL provide the ability to determine due and overdue ordered immunizations and render a notification. |  |
| Realization SHALL  Source -> Destination | Public  Immunization Administration Record | Public  CP.6.2#16 The system SHALL provide the ability to render the immunization order as written (i.e., exact clinician order language) when rendering administration information. |  |
| Realization SHALL  Source -> Destination | Public  Immunization Administration Record | Public  CP.6.2#21 The system SHALL provide the ability to capture the receiving entity (e.g., patient, representative, organization) when patient education information is provided at the time of immunization administration. |  |
| Realization SHALL  Source -> Destination | Public  Immunization Administration Record | Public  CP.6.2#18 The system SHALL provide the ability to render a patient educational information regarding the administration (e.g., Vaccine Information Statement (VIS)). |  |
| Realization SHALL  Source -> Destination | Public  Immunization Administration Record | Public  CP.6.2#19 The system SHALL provide the ability to capture that patient educational information (e.g., VIS) was provided at the time of immunization administration. |  |
| Realization SHALL  Source -> Destination | Public  Immunization Administration Record | Public  CP.6.2#21 The system SHALL provide the ability to capture the receiving entity (e.g., patient, representative, organization) when patient education information is provided at the time of immunization administration. |  |
| Realization SHALL  Source -> Destination | Public  Immunization Administration Record | Public  CP.6.2#16 The system SHALL provide the ability to render the immunization order as written (i.e., exact clinician order language) when rendering administration information. |  |
| Realization SHALL  Source -> Destination | Public  Immunization Administration Record | Public  CP.6.2#20 The system SHALL provide the ability to capture documentation that patient educational information (e.g., VIS) was provided at the time of immunization administration. |  |
| Realization SHOULD  Source -> Destination | Public  Immunization Administration Record | Public  CP.6.2#22 The system SHOULD provide the ability to capture and maintain immunization refusal reasons as discrete data. |  |
| Realization SHOULD  Source -> Destination | Public  Immunization Administration Record | Public  CP.6.2#23 The system SHOULD provide the ability to capture patient preferences regarding receipt of immunization (e.g. refusal of certain vaccine types) at time of immunization administration. |  |
| Realization SHOULD  Source -> Destination | Public  Immunization Administration Record | Public  CP.6.2#23 The system SHOULD provide the ability to capture patient preferences regarding receipt of immunization (e.g. refusal of certain vaccine types) at time of immunization administration. |  |

Attributes

| **Attribute** | **Notes** | **Constraints and tags** |
| --- | --- | --- |
| **date (recommended booster)**  Public |  | *Default:* |
| **immunization type**  Public |  | *Default:* |
| **series (immunization)**  Public |  | *Default:* |
| **dose**  Public |  | *Default:* |
| **educational information received** boolean  Private |  | *Default:* |
| **encounter**  Private |  | *Default:* |
| **future booster**  Private |  | *Default:* |
| **healthcare organization**  Private |  | *Default:* |
| **immunization order**  Private |  | *Default:* |
| **immunization provider**  Private |  | *Default:* |
| **justification-immunization refusal**  Private    «SHOULD» |  | *Default:* |
| **lot**  Private |  | *Default:* |
| **manufacturer**  Private |  | *Default:* |
| **ordered immunization due date**  Private |  | *Default:* |
| **patient preference for immunization**  Private |  | *Default:* |
| **receiving entity (educational information)**  Private |  | *Default:* |
| **refusal of vaccine type**  Private |  | *Default:* |
| **route of administration**  Private |  | *Default:* |
| **time (administration)**  Private |  | *Default:* |
| **type**  Private |  | *Default:* |
| **AllergyIntolerance and Adverse Reaction** link  Public | CP.6.2#04 The system SHOULD provide the ability to capture, in a discrete field, an allergy/adverse reaction to a specific **im**munization. | *Default:* |
| **Event** link  Private |  | *Default:* |
| **Medication** link  Private |  | *Default:* |
| **Patient** link  Private |  | *Default:* |
| **Provider** link  Private |  | *Default:* |

Operations

| **Method** | **Notes** | **Parameters** |
| --- | --- | --- |
| **auto-populate()**  Public «MAY» |  |  |
| **render()**  Public «SHALL» |  |  |
| **capture()**  Public «SHALL» |  |  |
| **maintain()**  Public «SHALL» |  |  |
| **transmit()**  Public «SHOULD» |  |  |

#### Immunization Future Booster

Type: **Class**

Status: Proposed. Version 1.0. Phase 1.0.

Package: EHR-S FIM CP.6.2 Immunization Management Keywords:

Detail: *Created on* *1/10/2012*. *Last modified on 11/4/2013*.

GUID: {EC9BA47E-07BE-4c19-ABAA-8CABBA7629B9}

| Custom Properties | |
| --- | --- |
|  | isActive = False |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| Association  Unspecified | Public  Immunization Future Booster | Public  Immunization Administration Record |  |

Attributes

| **Attribute** | **Notes** | **Constraints and tags** |
| --- | --- | --- |
| **immunization type**  Private |  | *Default:* |
| **recommended date**  Private |  | *Default:* |

#### Immunization History

Type: **Class** Treatments

Status: Proposed. Version 1.0. Phase 1.0.

Package: EHR-S FIM CP.6.2 Immunization Management Keywords:

Detail: *Created on* *1/10/2012*. *Last modified on 11/20/2013*.

GUID: {B860D28B-757A-4e97-B0BF-35561EAB5D07}

| Responsibilities (external requirements) | |
| --- | --- |
|  | CP.1.6#01 The system SHALL provide the ability to manage all immunizations associated with a patient. *(Proposed, Medium difficulty)* |
|  | CP.6.2#08 The system SHALL provide the ability to render a patient‘s immunization history upon request for appropriate authorities such as schools or day-care centers. *(Proposed, Medium difficulty)* |
|  | CP.6.2#12 The system SHOULD harmonize Immunization histories with a public health immunization registry according to scope of practice, organizational policy and/or jurisdictional law. *(Proposed, Medium difficulty)* |
|  | CP.6.2#13 The system SHOULD capture and render immunization histories from a public health immunization registry. *(Proposed, Medium difficulty)* |
|  | CP.6.2#13 The system SHOULD capture and render immunization histories from a public health immunization registry. *(Proposed, Medium difficulty)* |
|  | CP.6.2#14 The system SHALL conform to function CP.1.6 (Manage Immunization List). *(Proposed, Medium difficulty)* |
|  | CP.6.2#15 The system SHOULD provide the ability to update immunization histories at the time of capturing an immunization administration. *(Proposed, Medium difficulty)* |
|  | CP.6.2#15 The system SHOULD provide the ability to update immunization histories at the time of capturing an immunization administration. *(Proposed, Medium difficulty)* |

| Custom Properties | |
| --- | --- |
|  | isActive = False |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| Realization  Source -> Destination | Public  Immunization History | Public  CP.6.2#14 The system SHALL conform to function CP.1.6 (Manage Immunization List). |  |
| Realization  Source -> Destination | Public  CP.6.2#11 The system SHOULD exchange immunization histories with public health immunization registries according to scope of practice, organizational policy and/or jurisdictional law. | Public  Immunization History |  |
| Realization  Source -> Destination | Public  Immunization History | Public  CP.6.2#13 The system SHOULD capture and render immunization histories from a public health immunization registry. |  |
| Realization  Source -> Destination | Public  CP.1.6#04 The system SHOULD provide the ability to render a report of a patient's immunization history (e.g., for appropriate authorities such as schools, day-care centers or public health immunization registries) according to scope of practice, organizat | Public  Immunization History |  |
| Realization  Source -> Destination | Public  Immunization History | Public  CP.1.6#01 The system SHALL provide the ability to manage all immunizations associated with a patient. |  |
| Realization  Source -> Destination | Public  Immunization History | Public  CP.6.2#08 The system SHALL provide the ability to render a patient‘s immunization history upon request for appropriate authorities such as schools or day-care centers. |  |
| Realization  Source -> Destination | Public  Immunization History | Public  CP.6.2#12 The system SHOULD harmonize Immunization histories with a public health immunization registry according to scope of practice, organizational policy and/or jurisdictional law. |  |
| Generalization  Source -> Destination | Public  Immunization History | Public  Treatments |  |
| Realization  Source -> Destination | Public  Immunization History | Public  CP.6.2#13 The system SHOULD capture and render immunization histories from a public health immunization registry. |  |
| Realization SHOULD  Source -> Destination | Public  Immunization History | Public  CP.6.2#15 The system SHOULD provide the ability to update immunization histories at the time of capturing an immunization administration. |  |
| Realization SHOULD  Source -> Destination | Public  Immunization History | Public  CP.6.2#15 The system SHOULD provide the ability to update immunization histories at the time of capturing an immunization administration. |  |

Operations

| **Method** | **Notes** | **Parameters** |
| --- | --- | --- |
| **manage()**  Public «SHALL» |  |  |
| **capture()**  Private «SHOULD» |  |  |
| **exchange()**  Private |  |  |
| **harmonize()**  Private |  |  |
| **render()**  Public «SHALL» |  |  |
| **update()**  Private «SHOULD» |  |  |

#### Immunization List --DEPRECIATED --> Immunization History

Type: **Class**

Status: Proposed. Version 1.0. Phase 1.0.

Package: EHR-S FIM CP.6.2 Immunization Management Keywords:

Detail: *Created on* *1/10/2012*. *Last modified on 11/4/2013*.

GUID: {083FA256-B89E-4d19-BC02-D2E765C2B7CB}

| Custom Properties | |
| --- | --- |
|  | isActive = False |

Operations

| **Method** | **Notes** | **Parameters** |
| --- | --- | --- |
| **analyze()**  Public |  |  |
| **manage()**  Public |  |  |

#### Immunization Schedule

Type: **Class** Order Set, Schedule

Status: Proposed. Version 1.0. Phase 1.0.

Package: EHR-S FIM CP.6.2 Immunization Management Keywords:

Detail: *Created on* *2/7/2012*. *Last modified on 11/20/2013*.

GUID: {8922AF44-BABE-456d-ADE6-18261E0817DF}

| Responsibilities (external requirements) | |
| --- | --- |
|  | CP.6.2#03 The system SHALL provide the ability to determine and render required immunizations, and when they are due, based on widely accepted immunization schedules, when rendering encounter information. *(Proposed, Medium difficulty)* |
|  | CP.6.2#03 The system SHALL provide the ability to determine and render required immunizations, and when they are due, based on widely accepted immunization schedules, when rendering encounter information. *(Proposed, Medium difficulty)* |
|  | CP.6.2#07 The system SHALL provide the ability to maintain the immunization schedule. *(Proposed, Medium difficulty)* |

| Custom Properties | |
| --- | --- |
|  | isActive = False |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| Realization  Source -> Destination | Public  Immunization Schedule | Public  CP.6.2#07 The system SHALL provide the ability to maintain the immunization schedule. |  |
| Realization  Source -> Destination | Public  Immunization Schedule | Public  CP.6.2#03 The system SHALL provide the ability to determine and render required immunizations, and when they are due, based on widely accepted immunization schedules, when rendering encounter information. |  |
| Generalization  Source -> Destination | Public  Immunization Schedule | Public  Order Set |  |
| Realization  Source -> Destination | Public  Immunization Schedule | Public  CP.6.2#03 The system SHALL provide the ability to determine and render required immunizations, and when they are due, based on widely accepted immunization schedules, when rendering encounter information. |  |
| Generalization is-a  Source -> Destination | Public  Immunization Schedule | Public  Schedule |  |

Operations

| **Method** | **Notes** | **Parameters** |
| --- | --- | --- |
| **determine()**  Public «SHALL» |  |  |
| **maintain()**  Public «SHALL» |  |  |
| **render()**  Public «SHALL» |  |  |

#### Immunization Witheld Event

Type: **Class** Immunization Administration Record

Status: Proposed. Version 1.0. Phase 1.0.

Package: EHR-S FIM CP.6.2 Immunization Management Keywords:

Detail: *Created on* *1/10/2012*. *Last modified on 11/4/2013*.

GUID: {3B2E5ACA-6EDF-4326-8431-1FAE25A8BC54}

| Responsibilities (external requirements) | |
| --- | --- |
|  | CP.1.6#03 The system SHALL provide the ability to manage, as discrete elements, data associated with any immunization withheld (including date and time, immunization type, series, exception reason and immunization-withholding provider). *(Proposed, Medium difficulty)* |

| Custom Properties | |
| --- | --- |
|  | isActive = False |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| Realization  Source -> Destination | Public  Immunization Witheld Event | Public  CP.1.6#03 The system SHALL provide the ability to manage, as discrete elements, data associated with any immunization withheld (including date and time, immunization type, series, exception reason and immunization-withholding provider). |  |
| NoteLink  Source -> Destination | Public  Immunization Witheld Event | Public  <anonymous> |  |
| Generalization is-a  Source -> Destination | Public  Immunization Witheld Event | Public  Immunization Administration Record |  |

Attributes

| **Attribute** | **Notes** | **Constraints and tags** |
| --- | --- | --- |
| **exception reason**  Public |  | *Default:* |
| **withholding provider**  Public |  | *Default:* |

### FHIR

Type: Package

Status: Proposed. Version 1.0. Phase 1.0.

Package: Nov 2013 Prototype CP.6.2 Immunization Management Interoperability Specification

Detail: *Created on 11/5/2013*. *Last modified on 11/5/2013*

GUID: {1CD6341C-B3D8-4e78-9B26-EE637F2033F7}

**FHIR-FHIM High-Level Specification for Allergy, Intolerance and Adverse Reaction** - *(Class diagram)*

Created By: Steve Hufnagel *on* 11/7/2013

Last Modified: 11/20/2013

Version: Prototype. *Locked:* False

GUID: {9BB6F24E-795F-4289-A209-8B4A570F8862}

**This diagram illustrates how FHIR can be used to add implementation design-specification fidelity to the EHR-S FIM data-requirements conformance criteria (CC) for Allergy, Intolerance and Adverse Reaction.**

Fast Healthcare Interoperability Resources (**FHIR**, pronounced "Fire") defines a set of "Resources" that represent granular clinical concepts. The resources can be managed in isolation, or aggregated into complex documents. This flexibility offers coherent solutions for a range of interoperability problems. The simple direct definitions of the resources are based on thorough requirements gathering, formal analysis and extensive cross-mapping to other relevant standards. A workflow management layer provides support for designing, procuring, and integrating solutions. Technically, FHIR is designed for the web; the resources are based on simple XML, with an http-based RESTful protocol where each resource has predictable URL. Where possible, open internet standards are used for data representation.



Figure: 6

**FHIR Specification for Allergy, Intolerance and Adverse Reaction** - *(Class diagram)*

Created By: Steve Hufnagel *on* 11/5/2013

Last Modified: 11/20/2013

Version: Prototype. *Locked:* False

GUID: {3CD57CA7-86EA-4b93-9407-CE4085244536}

**This diagram illustrates how FHIR can be used to add implementation design-specification fidelity to the EHR-S FIM data-requirements conformance criteria (CC) for Allergy, Intolerance and Adverse Reaction.**

Fast Healthcare Interoperability Resources (**FHIR**, pronounced "Fire") defines a set of "Resources" that represent granular clinical concepts. The resources can be managed in isolation, or aggregated into complex documents. This flexibility offers coherent solutions for a range of interoperability problems. The simple direct definitions of the resources are based on thorough requirements gathering, formal analysis and extensive cross-mapping to other relevant standards. A workflow management layer provides support for designing, procuring, and integrating solutions. Technically, FHIR is designed for the web; the resources are based on simple XML, with an http-based RESTful protocol where each resource has predictable URL. Where possible, open internet standards are used for data representation.



Figure: 7

#### AdverseReaction

Type: **Class**

Status: Proposed. Version 1.0. Phase 1.0.

Package: FHIR Keywords:

Detail: *Created on* *11/4/2013*. *Last modified on 11/17/2013*.

GUID: {84D4DF98-D97D-4027-883F-FD986BB95180}

LINK to [FHIR AdverseReaction](http://www.hl7.org/implement/standards/fhir/adversereaction.html)

Adverse Reaction resources are used to provide information about specific reactions to a substance. These are normally associated with an [AllergyIntolerance](allergyintolerance.html) resource, but can be reported on their own when no assumption of further reactions is being made, or when specific events are being described.

An Adverse Reaction normally has a set of signs or symptoms that are reported in the Symptom class. However, it is possible to convey that an adverse reaction occurred without knowing the specific signs or symptoms that occurred, e.g. *Some unknown reaction occurred.* Similarly, it is possible to convey that an adverse reaction with a set of symptoms occurred but not indicate the substance if it is not known. e.g. *A rash occurred for some unknown reason.*

The Exposure class is used to indicate a set of exposures that preceded the reaction. There is no assertion of causality, purely a statement of timing. Each exposure can indicate a substance that might be different from the reaction if needed.

**Vocabulary Bindings**

The vocabulary bindings are tentative at this point. Further guidance is needed on whether the current bindings are reasonable.

ExposureType is currently a code, but if a suitable value set was used, it could (should?) be changed to a CodeableConcept.

| Custom Properties | |
| --- | --- |
|  | isActive = False |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| Realization  Source -> Destination | Public  AdverseReaction | Public  Clinical Resources |  |
| Aggregation exposure  Source -> Destination | Public  Exposure | Public  AdverseReaction | **AdverseReaction.exposure**  Definition An exposure to a substance that preceded a reaction occurrence.  **Control** 0..\* |
| Realization realize  Source -> Destination | Public  AdverseReaction | Public  Allergy, Intolerance and Adverse Reaction |  |
| Realization realize  Source -> Destination | Public  AdverseReactionReportingEvent | Public  AdverseReaction |  |
| Aggregation symptom  Source -> Destination | Public  Symptom | Public  AdverseReaction | AdverseReaction.symptom  Definition The signs and symptoms that were observed as part of the reaction.  Control 0..\*  Aliases Signs; Symptoms; Manifestations |

Attributes

| **Attribute** | **Notes** | **Constraints and tags** |
| --- | --- | --- |
| **identifier**  Public    [0..\*] | Definition This records identifiers associated with this reaction that are defined by business processed and/ or used to refer to it when a direct URL refernce to the resource itself is not appropriate (e.g. in CDA documents, or in written / printed documentation). [Control](resources.html%20l%20conformance) 0..\* [Type](datatypes.html) [Identifier](datatypes.html%20l%20Identifier) Requirements Need to allow connection to a wider workflow. | *Default:* |
| **reactionDate** dateTime  Public    [0..1] | Definition When the reaction occurred. [Control](resources.html%20l%20conformance) 0..1 [Type](datatypes.html) [dateTime](datatypes.html%20l%20dateTime) | *Default:* |
| **subject** link  Public | Definition The subject of the adverse reaction.  Control 1..1  Type Resource(Patient) | *Default:* |
| **didNotOccurFlag** boolean  Public | Definition To say that a reaction to substance did not occur.  Control 1..1  Type boolean  Is Modifier true  Comments Note that the normal case is false, which is a double negative - it's not true that this reaction did not occur. The normal case is to assert that a reaction did happen. | *Default:* |
| **recorder** link  Public    [0..1] | AdverseReaction.recorder  Definition Who recorded the reaction.  Control 0..1  Type Resource(Practitioner|Patient) | *Default:* |

#### AllergyIntolerance

Type: **Class**

Status: Proposed. Version 1.0. Phase 1.0.

Package: FHIR Keywords:

Detail: *Created on* *11/4/2013*. *Last modified on 11/17/2013*.

GUID: {3D9DE198-F793-4321-B36C-D7A07B2EC62D}

Link to FHIR website [AllergyIntolerance](http://www.hl7.org/implement/standards/fhir/allergyintolerance.html)

**Resource AllergyIntolerance - Content**

Allergy/Intolerance resources are used to provide information about adverse sensitivities to substances that lead to physiologic changes that are clinically observable. An adverse sensitivity is defined as:

A condition expected to result in undesirable physiologic reaction to an amount of a substance that would not produce a reaction in most individuals. The substance is the trigger of an immunologic response that produces the observed physiologic changes, or in some instances nonimmunologic mechanisms that produce clinically identical physiologic changes. The immunologic response might be considered the actual cause of the reaction, but it is exposure to the trigger substance that is clinically observable.

This definition excludes clinically identical episodes that may be caused by physical agents, such as heat, cold, sunlight, or vibration, by exercise activity, or by infectious agents. Those conditions caused by physical agents or infectious would be captured on the problem list (List/Condition Resources). The allergy/intolerance list is a list of conditions that represent a propensity unique to this individual for a reaction upon future exposure to a specified substance.

Note that this specification draws a distinction between the patients condition/problem list and an allergy/intolerance list, even though allergies and intolerances are also conditions. This is because the distinction is a long established clinical workflow, even to patients. Asking an individual "if they have any problems" is not going to invoke an account of their past reactions to medications or foods. Instead, they are asked if they "have any allergies". An allergy/intolerance is also different in that a potential harm from exposure to an external substance that may be ordered by a provider in the course of their care but is not inherent to exposure to that substance for the general population.

Most of the details of the sensitivity can be found in the set of reactions that are associated with the resource, though these may not be present when the patient has not provided enough information. Adverse Reactions do not have to be always associated with an AllergyIntolerance which may appropriate when an single reaction has not provided enough evidence for a meaningful Allergy/Intolerance, or in specific views of events rather than in a general clinical record.

**Criticality vs Severity**

Criticality is defined as "The potential seriousness of 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 allergic condition, not the reaction(s).

High criticality does not equate to a future severe reaction, but rather the potential for a severe and life-threatening reaction. Most reaction types are dose dependent, including anaphylaxis. Therefore, although they have a sensitivity of high criticality, exposure to a small dose of the substance to which they are sensitive might result in only a mild reaction. Severity of the reaction is also dependent on the route of exposure, but criticality since it applies to the condition, is not.

| Custom Properties | |
| --- | --- |
|  | isActive = False |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| Realization realize  Source -> Destination | Public  AllergyIntolerance | Public  Allergy, Intolerance and Adverse Reaction |  |
| Realization realize  Source -> Destination | Public  IntoleranceConditionEntry | Public  AllergyIntolerance |  |

Attributes

| **Attribute** | **Notes** | **Constraints and tags** |
| --- | --- | --- |
| **identifier** Identifier  Public    [0..1] | AllergyIntolerance.identifier  Definition This records identifiers associated with this allergy/intolerance concern that are defined by business processed and/ or used to refer to it when a direct URL refernce to the resource itself is not appropriate (e.g. in CDA documents, or in written / printed documentation).  Control 0..\*  Type Identifier | *Default:* |
| **criticality** code  Public    [0..1] | AllergyIntolerance.criticality  Definition Criticality of the sensitivity.  Control 0..1  Binding Criticality : The criticality of an adverse sensitivity (see http://hl7.org/fhir/criticality for values)  Type code | *Default:* |
| **sensitivityType** code  Public | AllergyIntolerance.sensitivityType  Definition Type of the sensitivity.  Control 1..1  Binding SensitivityType : The type of an adverse sensitivity (see http://hl7.org/fhir/sensitivitytype for values)  Type code | *Default:* |
| **recordedDate** dateTime  Public    [0..1] | AllergyIntolerance.recordedDate  Definition Date when the sensitivity was recorded.  Control 0..1  Type dateTime | *Default:* |
| **status** code  Public | AllergyIntolerance.status  Definition Suspected, Confirmed, Refuted, Resolved.  Control 1..1  Binding SensitivityStatus : The status of the adverse sensitivity (see http://hl7.org/fhir/sensitivitystatus for values)  Type code  Is Modifier true | *Default:* |
| **subject** Resource(Patient)  Public | AllergyIntolerance.subject  Definition Who the sensitivity is for.  Control 1..1  Type Resource(Patient) | *Default:* |
| **recorder** Resource(Practitioner|Patient)  Public | Definition Who recorded the sensitivity.  Control 0..1  Type Resource(Practitioner|Patient) | *Default:* |
| **substance** Resource(Substance)  Public | AllergyIntolerance.substance  Definition The substance that causes the sensitivity.  Control 1..1  Type Resource(Substance) | *Default:* |
| **reaction** Resource(AdverseReaction)  Public    [0..1] | AllergyIntolerance.reaction  Definition Reactions associated with the sensitivity.  Control 0..\*  Type Resource(AdverseReaction) | *Default:* |
| **sensitivityTest** Resource(Observation)  Public    [0..1] | AllergyIntolerance.sensitivityTest  Definition Observations that confirm or refute the sensitivity.  Control 0..\*  Type Resource(Observation) | *Default:* |

#### Exposure

Type: **Class**

Status: Proposed. Version 1.0. Phase 1.0.

Package: FHIR Keywords:

Detail: *Created on* *11/4/2013*. *Last modified on 11/7/2013*.

GUID: {C9F31607-5471-4853-BA8B-843BCF8AF5A3}

LINK to FHIR web-site page for [AdverseReaction](http://www.hl7.org/implement/standards/fhir/adversereaction.html) is http://www.hl7.org/implement/standards/fhir/adversereaction.html

**AdverseReaction.exposure**

**Definition:** An exposure to a substance that preceded a reaction occurrence.

[Control](resources.html%20l%20conformance) 0..\*

| Custom Properties | |
| --- | --- |
|  | isActive = False |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| Aggregation exposure  Source -> Destination | Public  Exposure | Public  AdverseReaction | **AdverseReaction.exposure**  Definition An exposure to a substance that preceded a reaction occurrence.  **Control** 0..\* |

Attributes

| **Attribute** | **Notes** | **Constraints and tags** |
| --- | --- | --- |
| **exposure.exposureDate** dateTime  Public    [0..1] | AdverseReaction.exposure.exposureDate  Definition When the exposure occurred.  Control 0..1  Type dateTime | *Default:* |
| **exposure.exposureType** code  Public    [0..1] | AdverseReaction.exposure.exposureType  Definition Drug Administration, Immunization, Coincidental.  Control 0..1  Binding ExposureType : The type of exposure that resulted in an adverse reaction (see http://hl7.org/fhir/exposureType for values)  Type code | *Default:* |
| **exposure.causalityExpectation** code  Public    [0..1] | AdverseReaction.exposure.causalityExpectation  Definition A statement of how confident that the recorder was that this exposure caused the reaction.  Control 0..1  Binding CausalityExpectation : How likely is it that the given exposure caused a reaction (see http://hl7.org/fhir/causalityExpectation for values)  Type code | *Default:* |
| **exposure.substance** Resource(Substance)  Public    [0..1] | AdverseReaction.exposure.substance  Definition Substance(s) that is presumed to have caused the adverse reaction.  Control 0..1  Type Resource(Substance) | *Default:* |
| **AllergyIntolerance.sensitivityType** code  Public | AllergyIntolerance.sensitivityType  Definition Type of the sensitivity.  Control 1..1  Binding SensitivityType : The type of an adverse sensitivity (see http://hl7.org/fhir/sensitivitytype for values)  Type code | *Default:* |
| **recordedDate** dateTime  Public    [0..1] | AllergyIntolerance.recordedDate  Definition Date when the sensitivity was recorded.  Control 0..1  Type dateTime | *Default:* |
| **status** code  Public | AllergyIntolerance.status  Definition Suspected, Confirmed, Refuted, Resolved.  Control 1..1  Binding SensitivityStatus : The status of the adverse sensitivity (see http://hl7.org/fhir/sensitivitystatus for values)  Type code  Is Modifier true | *Default:* |
| **subject** Resource(Patient)  Public | AllergyIntolerance.subject  Definition Who the sensitivity is for.  Control 1..1  Type Resource(Patient) | *Default:* |
| **recorder** Resource(Practitioner|Patient)  Public | Definition Who recorded the sensitivity.  Control 0..1  Type Resource(Practitioner|Patient) | *Default:* |
| **substance** Resource(Substance)  Public | AllergyIntolerance.substance  Definition The substance that causes the sensitivity.  Control 1..1  Type Resource(Substance) | *Default:* |
| **reaction** Resource(AdverseReaction)  Public    [0..1] | AllergyIntolerance.reaction  Definition Reactions associated with the sensitivity.  Control 0..\*  Type Resource(AdverseReaction) | *Default:* |

#### Symptom

Type: **Class**

Status: Proposed. Version 1.0. Phase 1.0.

Package: FHIR Keywords:

Detail: *Created on* *11/4/2013*. *Last modified on 11/7/2013*.

GUID: {E28505DE-1316-49ae-8E3F-CB1CDF3BF200}

LINK to FHIR web-site page for [AdverseReaction](http://www.hl7.org/implement/standards/fhir/adversereaction.html) is http://www.hl7.org/implement/standards/fhir/adversereaction.html

**AdverseReaction.symptom**

Definition The signs and symptoms that were observed as part of the reaction.

**Aliases:** Signs; Symptoms; Manifestations

| Custom Properties | |
| --- | --- |
|  | isActive = False |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| Aggregation symptom  Source -> Destination | Public  Symptom | Public  AdverseReaction | AdverseReaction.symptom  Definition The signs and symptoms that were observed as part of the reaction.  Control 0..\*  Aliases Signs; Symptoms; Manifestations |

Attributes

| **Attribute** | **Notes** | **Constraints and tags** |
| --- | --- | --- |
| **code** CodeableConcept  Public | AdverseReaction.symptom.code  Definition Indicates the specific sign or symptom that was observed.  Control 1..1  Binding SymptomType : see ICD-10 Reaction codes  Type CodeableConcept | *Default:* |
| **severity** ReactionSeverity  Public    [0..1] | AdverseReaction.symptom.severity  Definition The severity of the sign or symptom.  Control 0..1  Binding ReactionSeverity : The severity of an adverse reaction. (see http://hl7.org/fhir/reactionSeverity for values)  Type code | *Default:* |

#### Fast Healthcare Interoperability Resource

Type: **Class**

Status: Proposed. Version 1.0. Phase 1.0.

Package: FHIR Keywords:

Detail: *Created on* *11/5/2013*. *Last modified on 11/5/2013*.

GUID: {5B43E53B-57DB-4287-B7ED-BAE9B9C98C7E}

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| Custom Properties | |
| --- | --- |
|  | isActive = False |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| Aggregation  Source -> Destination | Public  Clinical Resources | Public  Fast Healthcare Interoperability Resource |  |

Attributes

| **Attribute** | **Notes** | **Constraints and tags** |
| --- | --- | --- |
| **Clinical Resources** link  Public | Resources that provide core clinical record keeping - focused on the content of the provider/patient encounter | *Default:* |
| **Administrative Resources** link  Public | Track individuals and organizations involved in the provision of healthcare | *Default:* |
| **Infrastructure** link  Public | Generally useful resources whereever resources are used | *Default:* |

#### Clinical Resources

Type: **Class**

Status: Proposed. Version 1.0. Phase 1.0.

Package: FHIR Keywords:

Detail: *Created on* *11/5/2013*. *Last modified on 11/5/2013*.

GUID: {5C56A095-C9D1-42a9-AECF-A4F6B834D7A3}

| Custom Properties | |
| --- | --- |
|  | isActive = False |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| Realization  Source -> Destination | Public  AdverseReaction | Public  Clinical Resources |  |
| Aggregation  Source -> Destination | Public  Clinical Resources | Public  Fast Healthcare Interoperability Resource |  |

### FHIM

Type: Package

Status: Proposed. Version 1.0. Phase 1.0.

Package: Nov 2013 Prototype CP.6.2 Immunization Management Interoperability Specification

Detail: *Created on 11/6/2013*. *Last modified on 11/7/2013*

GUID: {AE46D10C-8455-4898-AE92-932C2BA332C6}

**FHIM Allergy, Intolerance and Adverse Reaction** - *(Class diagram)*

Created By: Steve Hufnagel *on* 11/6/2013

Last Modified: 11/18/2013

Version: Prototype. *Locked:* False

GUID: {D51F4039-59BD-4c55-8854-DD4BA6913EE1}

[Federal Health Information Model](http://www.fhims.org/) http://www.fhims.org/

The FHA, together with its federal partners, addresses Executive Order 13410 to achieve secure, interoperable health information exchanges within the federal government and its consortia. FHA serves a coordinating and convening role across the federal agencies to support alignment of health information technology (IT) investments. This has led to the Federal Health Interoperability Modeling (FHIM) Initiative, Federal Health Information Planning and Reporting (FHIPR), and other projects aimed at coordinating across federal agencies. The FHIM is a model of healthcare data developed for the FHA partner agencies. The FHIM project seeks to develop a common Logical Information Model or Computationally Independent Model (CIM).

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.

Acts, Roles, and EntitiesThe 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. Many of the partner agencies are already active in some of these SDOs, in which case the FHIMS program can help agencies speak with a single voice at the SDOs while also reducing redundant participation. For those agencies that do not yet have a presence in a particular SDO, this program provides a mechanism for agencies to delegate issues to another agency. For example, if the Department of Veterans Affairs (VA) is active in the Organization for the Advancement of Structured Information Standards (OASIS), and the Indian Health Service (IHS) is not, the FHIMS program provides an opportunity for IHS to learn of relevant OASIS activities, and for IHS to request the VA representatives to OASIS to champion a particular issue.

Another FHIMS initiative is the Federal Health Terminology Model project, which coordinates partner agency efforts to develop healthcare terminology models (i.e., new content), 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. The Information Modeling team will work very closely with the Terminology Modeling team to identify those concepts which should be enumerated in a value set, to define that value set, and to define the members of the value set.



Figure: 8

**FHIM Adverse-Event Reporting Domain** - *(Class diagram)*

Created By: Steve Hufnagel *on* 11/7/2013

Last Modified: 11/20/2013

Version: Prototype. *Locked:* False

GUID: {AC28ACC3-174A-4a6b-9C6C-E06489F8A15F}

[Federal Health Information Model](http://www.fhims.org/) http://www.fhims.org/

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Another FHIMS initiative is the Federal Health Terminology Model project, which coordinates partner agency efforts to develop healthcare terminology models (i.e., new content), 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. The Information Modeling team will work very closely with the Terminology Modeling team to identify those concepts which should be enumerated in a value set, to define that value set, and to define the members of the value set.



Figure: 9

**FHIM Allergies Domain** - *(Class diagram)*

Created By: Steve Hufnagel *on* 11/6/2013

Last Modified: 11/20/2013

Version: Prototype. *Locked:* False

GUID: {8AFE24B4-91E7-4342-9EB3-67DB958284AE}

[Federal Health Information Model](http://www.fhims.org/) http://www.fhims.org/

The FHA, together with its federal partners, addresses Executive Order 13410 to achieve secure, interoperable health information exchanges within the federal government and its consortia. FHA serves a coordinating and convening role across the federal agencies to support alignment of health information technology (IT) investments. This has led to the Federal Health Interoperability Modeling (FHIM) Initiative, Federal Health Information Planning and Reporting (FHIPR), and other projects aimed at coordinating across federal agencies. The FHIM is a model of healthcare data developed for the FHA partner agencies. The FHIM project seeks to develop a common Logical Information Model or Computationally Independent Model (CIM).

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.

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Another FHIMS initiative is the Federal Health Terminology Model project, which coordinates partner agency efforts to develop healthcare terminology models (i.e., new content), 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. The Information Modeling team will work very closely with the Terminology Modeling team to identify those concepts which should be enumerated in a value set, to define that value set, and to define the members of the value set.



Figure: 10

#### Adverse Event

Type: Package

Status: Proposed. Version 1.0. Phase 1.0.

Package: FHIM

Detail: *Created on 11/6/2013*. *Last modified on 11/7/2013*

GUID: {B4919BE4-399F-456e-A91F-47C48440C61E}

##### AdverseReactionReportingEvent

Type: **Class** NotificationReport

Status: Proposed. Version 1.0. Phase 1.0.

Package: Adverse Event Keywords:

Detail: *Created on* *11/6/2013*. *Last modified on 11/17/2013*.

GUID: {4BD72B7F-6421-4a39-83E9-70E531F9D131}

AdverseEventReporting

Class AdverseReactionReportingEvent

When adverse event or suspected event is originally reported to a caregiver. Adverse Event: Any incident where the use of a medication (drug or biologic), at any dose, a medical device (including in vitro diagnostics) or a special nutritional product (e.g., dietary supplement, infant formula or medical food) is suspected to have resulted in an adverse outcome in a patient.

"Adverse Drug Reaction (ADR): A response to a medicinal product which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function. A causal relationship between the medicinal product and an AE should at least be a reasonable possibility. An ADR in post-marketing situations normally refers to ADRs occurring at therapeutic doses, but for the purposes of reporting any dosage should be considered.

Adverse Event (AE): Any untoward medical occurrence in a patient or clinical investigation subject administered the pharmaceutical product that does not necessarily have to have a causal relationship with the treatment for which the product is used. An AE can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the use of the medicinal (investigational) product, whether or not considered related to the medicinal (investigational) product. A pre-existing condition which, worsened in severity after administration of the product would also be considered as an adverse event." - Pharmacovigilance.org.uk

| Custom Properties | |
| --- | --- |
|  | isActive = False |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| Association  Source -> Destination | Public  AdverseReactionReportingEvent | Public intoleranceObservation  IntoleranceCondition |  |
| Association  Source -> Destination | Public  AdverseReactionReportingEvent | Public  IndividualProvider |  |
| Generalization  Source -> Destination | Public  AdverseReactionReportingEvent | Public  NotificationReport |  |
| Association  Source -> Destination | Public  AdverseReactionReportingEvent | Public relevantLabData  RelevantLabData |  |
| Association  Source -> Destination | Public  AdverseReactionReportingEvent | Public concommittantDrugs  ConcommittantDrugs |  |
| Association  Source -> Destination | Public  AdverseReactionReportingEvent | Public suspectedAgent  SuspectedAgent |  |
| Realization realize  Source -> Destination | Public  AdverseReactionReportingEvent | Public  AdverseReaction |  |

Attributes

| **Attribute** | **Notes** | **Constraints and tags** |
| --- | --- | --- |
| **comment** String  Public | Any comments or notes made in reference to the adverse event or suspected event. | *Default:* |
| **concommittantDrugs**  ConcommittantDrugs  Private    «SubstanceAdministration» |  | *Default:* |
| **congenitalAnomaly** boolean  Public |  | *Default:* |
| **dateDoctorNotified** PoinyInTime  Public    «TS» |  | *Default:* |
| **dateReportedToFda** PointInTime  Public |  | *Default:* TS |
| **dateReportedToMfr** PointInTime  Public |  | *Default:* TS |
| **dateReportedToVaers** PointInTime  Public    «TS» |  | *Default:* |
| **daysHospitalized** int  Public |  | *Default:* |
| **didPatientDieFromEvent** boolean  Public |  | *Default:* |
| **didPatientRecover** boolean  Public |  | *Default:* |
| **eventDateTime** OointInTime  Public    «TS» |  | *Default:* |
| **intoleranceObservation** IntoleranceCondition  Public    «Obersavation» |  | *Default:* |
| **isReporterACareProvider** boolean  Public | If the person reporting the Adverse Event is a Health Care Provider? Possible Values Include: Yes, No etc. | *Default:* |
| **otherRelatedHistory** String  Public |  | *Default:* |
| **patientConsentDate** PointInTime  Public    «TS» |  | *Default:* |
| **preExistingMedicalCondition** HealthConcern  Public    «Observation» |  | *Default:* |
| **relevantLabData** RelevantLabData  Public    «Observation» |  | *Default:* |
| **equiredErOrMdVisit** boolean  Public |  | *Default:* |
| **requiredHospitalization** boolean  Public |  | *Default:* |
| **requiredIntervention** boolean  Public |  | *Default:* |
| **resultedInPermanentDisability** boolean  Public |  | *Default:* |
| **resultedInProlongedHospitalization**  boolean  Public |  | *Default:* |
| **sendToFda** boolean  Public |  | *Default:* |
| **sendToMfr** boolean  Public |  | *Default:* |
| **severity** Code  Public    «CS» |  | *Default:* |
| **suspectedAgent** SuspectedAgent  Private |  | *Default:* Observation |
| **wasDiscloseIdToMfr** boolean  Private |  | *Default:* |
| **wasDoseRelated** int  Public |  | *Default:* |
| **wasEventLifeThreatening** boolean  Public |  | *Default:* |
| **wasReactionTreatedWithRx** boolean  Public |  | *Default:* |
| **wasRelatedToNewDrug** boolean  Public |  | *Default:* |
| **wasRelatedToTherapeuticFailure** boolean  Public |  | *Default:* |
| **wasSeriousADR** boolean  Public |  | *Default:* |
| **wasUnexpectedADR** boolean  Public |  | *Default:* |
| **witness** IndividualProvider  Public    «Role» |  | *Default:* |

##### ConcommittantDrugs

Type: **Class**

Status: Proposed. Version 1.0. Phase 1.0.

Package: Adverse Event Keywords:

Detail: *Created on* *11/7/2013*. *Last modified on 11/7/2013*.

GUID: {04602E1D-B060-4c4e-AB00-BC2831D41C13}

| Custom Properties | |
| --- | --- |
|  | isActive = False |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| Association  Source -> Destination | Public  AdverseReactionReportingEvent | Public concommittantDrugs  ConcommittantDrugs |  |
| Association  Source -> Destination | Public  ConcommittantDrugs | Public medicinalProduct  MedicinalProduct |  |

Attributes

| **Attribute** | **Notes** | **Constraints and tags** |
| --- | --- | --- |
| **adminSraetDate** PointInTime  Public    «TS» |  | *Default:* |
| **adminEndDate** PointInTime  Public    «TS» |  | *Default:* |
| **lastFillDate** PointInTime  Public    «TS» |  | *Default:* |
| **medicinalProduct** MedicinalProduct  Public    «ManufacturedMaterial» |  | *Default:* |

##### ReactionObservation

Type: **Class**

Status: Proposed. Version 1.0. Phase 1.0.

Package: Adverse Event Keywords:

Detail: *Created on* *11/6/2013*. *Last modified on 11/8/2013*.

GUID: {972562C7-6E9B-4ed0-9465-445AE14C6B98}

| Custom Properties | |
| --- | --- |
|  | isActive = False |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| Association  Source -> Destination | Public reaction  IntoleranceCondition | Public  ReactionObservation |  |
| Association  Source -> Destination | Public  ReactionObservation | Public author  IndividualProvider |  |
| NoteLink  Source -> Destination | Public  <anonymous> | Public  ReactionObservation |  |

Attributes

| **Attribute** | **Notes** | **Constraints and tags** |
| --- | --- | --- |
| **dateRecorded** PointInTime  Public | Date/time this allergy/adverse reaction was entered into the system. | *Default:* |
| **DateTimeObserved** PointinTime  Public | Date/time this allergy/adverse reaction was entered into the system. | *Default:* |
| **desctiption** string  Public | Provides a textual narrative of the Reaction observed for the intolerance event of the patient. | *Default:* |
| **reaction** CodeWithOriginalText  Public | Indicates the symptom observed that is suspected to have been caused by adverse reaction.  "Identifies the specific allergic reaction that was documented." - HL7 Version 2.8, AL1-5 and IAM-5 | *Default:* |
| **severity** CodeWithOriginalText  Public | Categorizes the intensity of the reaction event.  "Indicates the general severity of the allergy" - HL7 Version 2.8, AL1-4, IAM-4, and IAR-2. HL7 Version 2 has the following suggested values (table 128): Severe; Moderate; Mild; Unknown.  The Common Terminology Criteria for Adverse Events (CTCAE) has the following values:  Grade 1: Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated.  Grade 2: Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL\*.  Grade 3: Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self care ADL\*\*.  Grade 4: Life-threatening consequences; urgent intervention indicated.  Grade 5: Death related to AE. | *Default:* |
| **author** IndividualProvider  Private    «Role» |  | *Default:* |

##### RelevantLabData

Type: **Class**

Status: Proposed. Version 1.0. Phase 1.0.

Package: Adverse Event Keywords:

Detail: *Created on* *11/7/2013*. *Last modified on 11/7/2013*.

GUID: {2001EB0A-413A-4728-BA18-DAA4778C186F}

| Custom Properties | |
| --- | --- |
|  | isActive = False |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| Association  Source -> Destination | Public  AdverseReactionReportingEvent | Public relevantLabData  RelevantLabData |  |

Attributes

| **Attribute** | **Notes** | **Constraints and tags** |
| --- | --- | --- |
| **collectionDate** PointInTime  Public    «TS» |  | *Default:* |
| **results** String  Public |  | *Default:* |
| **test** String  Public |  | *Default:* |

##### SuspectedAgent

Type: **Class**

Status: Proposed. Version 1.0. Phase 1.0.

Package: Adverse Event Keywords:

Detail: *Created on* *11/7/2013*. *Last modified on 11/7/2013*.

GUID: {06A6A849-6F0A-4ff2-81CD-0028B9804A0E}

| Custom Properties | |
| --- | --- |
|  | isActive = False |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| Association  Source -> Destination | Public  SuspectedAgent | Public medicinalProduct  MedicinalProduct |  |
| Association  Source -> Destination | Public  AdverseReactionReportingEvent | Public suspectedAgent  SuspectedAgent |  |

Attributes

| **Attribute** | **Notes** | **Constraints and tags** |
| --- | --- | --- |
| **adminDuration** int  Public |  | *Default:* |
| **adminStartDate adminStartDate** PointInTime  Public    «TS» |  | *Default:* |
| **adminStoptDate** PointInTime  Public    «TS» |  | *Default:* |
| **adverseReactionLikelihood** Code  Public    «CS» |  | *Default:* |
| **dailyDose** String  Public |  | *Default:* |
| **didReactionCease** boolean  Public |  | *Default:* |
| **didReappear** boolean  Public |  | *Default:* |
| **doesNormallyOccur** boolean  Public |  | *Default:* |
| **indicationsForUse** String  Public |  | *Default:* |
| **lastFillDate** PointInTime  Private    «TS» |  | *Default:* |
| **medicinalProduct** MedicinalProduct  Public    «ManufacturedMaterial» |  | *Default:* |
| **nbrOfPreviousDoses** int  Public |  | *Default:* |
| **route route** String  Public |  | *Default:* |
| **wasAdminStopped** boolean  Public |  | *Default:* |
| **wasDueToPtCondition** int  Public |  | *Default:* |
| **wasReadministered** boolean  Public |  | *Default:* |

#### Allergies

Type: Package

Status: Proposed. Version 1.0. Phase 1.0.

Package: FHIM

Detail: *Created on 11/6/2013*. *Last modified on 11/6/2013*

GUID: {6FC6D6FB-789C-4d74-A382-CF9FEBB6C3B1}

##### InformationReporter

Type: **Class**

Status: Proposed. Version 1.0. Phase 1.0.

Package: Allergies Keywords:

Detail: *Created on* *11/6/2013*. *Last modified on 11/6/2013*.

GUID: {0A22D934-3990-401f-A78E-D1C2842DD652}

Allergies

Class InformationReporter

The person who reported information on the patient's behalf. This may be the patient him/herself. Note that because all we need is the person's name and contact information (address, phone numbers), this class does not have an association to the Person class (although logically it should). This is because the other properties of Person, such as sex and date of birth, are irrelevant to the usage. The HL7 Role class allows for names and addresses on the Role, which technically should be only those names or addresses as the relate to the role (i.e., as they differ from those in Person class), but since these are available for use, we are utilizing them in this manner, even though it is somewhat irregular.

| Custom Properties | |
| --- | --- |
|  | isActive = False |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| Association  Source -> Destination | Public  IntoleranceConditionEntry | Public  InformationReporter |  |

Attributes

| **Attribute** | **Notes** | **Constraints and tags** |
| --- | --- | --- |
| **legalName** PersonName  Public    «PN» | The name by which a person is known or legally identified such as the name on a driver's license or passport. Note that the datatype for this property is a PersonName, which includes the various parts that make up a person's name such as family name, prefixes, suffixes, etc.  "Contains the name of the person reporting the allergy to a caregiver at the time reported in [dateReported]" - HL7 Version 2.8, IAM-14 | *Default:* |
| **relationshipCategory** Code  Public    «CS» | "Contains the personal relationship that the person reporting the allergy has to the patient." - HL7 Version 2.8, IAM-15. HL7 Version 2 suggested values (table 63) include: Self; Spouse; Parent; Friend, etc. | *Default:* |

##### IntoleranceCondition

Type: **Class** IntoleranceConditionEntry

Status: Proposed. Version 1.0. Phase 1.0.

Package: Allergies Keywords:

Detail: *Created on* *11/6/2013*. *Last modified on 11/20/2013*.

GUID: {2701C845-949E-40cf-9FCF-4B1938B2BD0F}

Public «CS» Code alertDevice

"Describes any type of allergy alert device the patient may be carrying or wearing." - HL7 Version 2.8, IAM-16. HL7 Version 2 has the following suggested values (table 437): Bracelet; Necklace; Wallet Card.

| Custom Properties | |
| --- | --- |
|  | isActive = False |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| Generalization  Source -> Destination | Public  IntoleranceCondition | Public  IntoleranceConditionEntry |  |
| Association  Source -> Destination | Public reaction  IntoleranceCondition | Public  ReactionObservation |  |
| Association  Source -> Destination | Public author  IntoleranceCondition | Public  Author |  |
| Association  Source -> Destination | Public dataEnterer  IntoleranceCondition | Public  DataEntrer |  |
| Association  Source -> Destination | Public  IntoleranceCondition | Public verifier  Verifier |  |
| Association  Source -> Destination | Public  AdverseReactionReportingEvent | Public intoleranceObservation  IntoleranceCondition |  |

Attributes

| **Attribute** | **Notes** | **Constraints and tags** |
| --- | --- | --- |
| **alertDevice** Code  Public | Public «CS» Code alertDevice  "Describes any type of allergy alert device the patient may be carrying or wearing." - HL7 Version 2.8, IAM-16. HL7 Version 2 has the following suggested values (table 437): Bracelet; Necklace; Wallet Card. | *Default:* |
| **dateOfOnset** PointInTime  Public | Public «TS» PointInTime dateOfOnset  Datatypes  Class PointInTime  A data type containing date/time information. This data type is a placeholder, as various platforms have differing built-in date/time datatypes. It is anticipated that this data type will be replaced by a different data type when transforming to a particular implementation platform.  Date when this particular Intolerance Condition or Allergy first manifested itself or was confirmed via testing if it had not yet manifested itself.  "Contains the actual date of the first reaction." - HL7 Version 2.8, IAM-11 | *Default:* |
| **dateOfOnsetText** String  Public | Public String dateOfOnsetText  "Contains a text description of the time period of the first reaction when an exact date is not known (e.g., adolescence, childhood, spring 1990)." - HL7 Version 2.8, IAM-12 | *Default:* |
| **IntoleranceCategory** Code  Public | Public «CS» Code intoleranceCategory  Datatypes  Class Code  "A word, letter, number, or other symbol used in a code system to mark, represent, or identify something: The code on the label shows the date of manufacture." - Dictionary.com This \*abstract\* data type represents a "coded element" - some series of letters or numbers which can be "looked up" in a code system or value set. In practice, this data type will be substituted with specific "flavors" of the code data type for use in particular standards-based payloads.  Categorizes the intolerance along two axes: whether the reactant is a Drug, Food, or other substance, and whether the intolerence is a true allergy, an intolerance, or propensity to adverse reaction. Possible values are members of the SNOMED Allergy Event value set. This property is required for Meaningful Use.  "Indicates a general allergy category (drug, food, pollen, etc.)." - HL7 Version 2.8, AL1-2 and IAM-2. HL7 Version 2 has the following suggested values (table 127): Drug allergy; Food allergy; Miscellaneous allergy; Miscellaneous contraindication; Environmental Allergy; Animal Allergy; Plant Allergy; Pollen Allergy. | *Default:* |
| **isAbsolutelyContraIndicated** boolean  Public | Public Boolean isAbsolutelyContraIndicated | *Default:* |
| **mechanism** Code  Public | Public «CS» Code mechanism  Categorizes whether the underlying process (mechanism) of the Intolerance Condition is an Immunoglobulin-E (IgE)-mediated response, an exepected response to a pharmacologic substance, or unknown. Allergy: An allergy reaction must have symptoms (reaction) consistent with an actual allergy - rash, hives, severe swelling, redness, itchiness, difficulty breathing (due to swelling around breathing areas), etc. Pharmacologic: A pharmacologic reaction is an adverse event rather then an allergy. It is a reaction based on the pharmacologic properties of the drug and has to do with a reaction that can be expected due to the pharmacologic activity of the drug. It can occur when the patient takes the right amount or an amount greater or less than the recommended doses. Some examples are: an antidiarrheal agent (like Immodium) causing constipation, a laxative causing diarrhea, a beta blocker causing bradycardia (slow heart rate), furosemide (a diuretic) causing excessive urination, or a blood pressure medication causing low blood pressure (will be fully modeled in a subsequent phase). Unknown: An unknown reaction is a reaction experienced by the patient that cannot be explained by either of the other two mechanisms, for example, eating a pear and developing a cough or taking a blood pressure medication and developing right elbow pain. This type of reaction is consistent, disappears upon withdrawing the agent, and reappears when the agent or food item is restarted/eaten again.  "Contains the reason why the patient should not be exposed to a substance." - HL7 Version 2.8, IAM-9 and IAR-3. HL7 Version 2 has the following suggested values (table 436): Adverse Reaction (Not otherwise classified); Allergy; Contraindication; Intolerance; Side Effect. | *Default:* |
| **reactant** Code  Public | Public «CS» Code reactant  Identifies the substance to which the patient has an intolerance or allergy. The reactant will point to a value set, which will be a superset of valuesets for Drug Product, Drug Class, Ingredient, Food Product, and Environmental reactants.  "Uniquely identifies a particular allergen." - HL7 Version 2.8, AL1-3 and IAM-3  "Identifies the specific allergic reaction that was documented." - HL7 Version 2.8, IAR-1. | *Default:* |
| **reactantCategory** Code  Public | Public «CS» Code reactantCategory  Categorizes the reactant to which the patient has demonstrated an intolerance or an allergy. Possible values include Drug Product, Drug Class, Ingredient, Food Product, and Environmental. Note that this property may contain more than one value. | *Default:* |
| **criticality** CodeWithOriginalText  Private | Public «CD» CodeWithOriginalText criticality  Datatypes  Class CodeWithOriginalText  A specialization of Code which additionally contains a property to hold the original text as seen and/or selected by the user who entered the data  Categorizes the intensity of the reaction event.  "Indicates the general severity of the allergy" - HL7 Version 2.8, AL1-4, IAM-4, and IAR-2. HL7 Version 2 has the following suggested values (table 128): Severe; Moderate; Mild; Unknown.  The Common Terminology Criteria for Adverse Events (CTCAE) has the following values:  Grade 1: Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated.  Grade 2: Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL\*.  Grade 3: Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self care ADL\*\*.  Grade 4: Life-threatening consequences; urgent intervention indicated.  Grade 5: Death related to AE. | *Default:* |

##### IntoleranceConditionEntry

Type: **Class**

Status: Proposed. Version 1.0. Phase 1.0.

Package: Allergies Keywords:

Detail: *Created on* *11/6/2013*. *Last modified on 11/17/2013*.

GUID: {9D230A18-C580-4805-A789-1AD1C1D0D12C}

| Custom Properties | |
| --- | --- |
|  | isActive = False |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| Generalization  Source -> Destination | Public  NoKnownAllergyEntry | Public  IntoleranceConditionEntry |  |
| Generalization  Source -> Destination | Public  IntoleranceCondition | Public  IntoleranceConditionEntry |  |
| Association  Source -> Destination | Public comment  IntoleranceConditionEntry | Public  CommentEvent |  |
| Aggregation  Source -> Destination | Public intoleranceConditionEntry  IntoleranceConditionEntry | Public  IntoleranceConditionList |  |
| Association  Source -> Destination | Public RelatedIntoleranceCategory  IntoleranceConditionEntry | Public  RelatedIntoleranceCondition |  |
| Association  Source -> Destination | Public  RelatedIntoleranceCondition | Public IntoleranceConditionEntry  IntoleranceConditionEntry |  |
| Association  Source -> Destination | Public  IntoleranceConditionEntry | Public  InformationReporter |  |
| Association  Source -> Destination | Public  IntoleranceConditionEntry | Public serviceDeliveryLocation  ServiceDeliveryLocation |  |
| Realization realize  Source -> Destination | Public  IntoleranceConditionEntry | Public  AllergyIntolerance |  |

Attributes

| **Attribute** | **Notes** | **Constraints and tags** |
| --- | --- | --- |
| **dateRecorded** PointinTime  Public | Public «TS» PointInTime dateRecorded  Date/time this allergy/adverse reaction was entered into the system.  **Qualified Name** FHIM::Allergies::IntoleranceConditionEntry::dateRecorded  Type «TS» PointInTime | *Default:* |
| **DateReported** PointinTime  Public | Public «TS» PointInTime dateReported  "Contains the date/time the allergy was reported to a caregiver." - HL7 Version 2.8, IAM-13 | *Default:* |
| **id** Id  Private | Uniquely identifies the Intolerance Condition record.  "Contains a value that uniquely identifies a single allergy for a person" - HL7 Version 2.8, IAM-7 | *Default:* |
| **InformationSourceCategory** Code  Public | Public «CS» Code informationSourceCategory  Indicates whether the Intolerance Condition was observed by a clinician (or was medically verified) or was merely reported by the patient. Provides a measure of trustworthiness of the information. Note that in VistA, this is called Observed if observed by a clinician, or Historical if patient-reported. | *Default:* |
| **Status** Code  Public | Public «CS» Code status  A code specifying the state of the Intolerance Condition Observation record. See HL7 V3 Act.statusCode. Nothe that when the StatusCode is set to 'Nullified,' this indicates that the allergy record was entered in error.  "Indicates the verification status for the allergy." - HL7 Version 2.8, IAM-17. HL7 Version 2 has the following suggested values (table 438): Unconfirmed; Pending; Suspect; Confirmed or verified; Confirmed but inactive; Erroneous; Doubt raised. | *Default:* |
| **serviceDeliveryLocation** ServiceDeliveryLocation  Private    «Role» | The location at which the Intolerance condition was noted. | *Default:* |
| **author** Author  Private    «Participation» | "A party that originates the Act and therefore has responsibility for the information given in the Act and ownership of this Act." - HL7 V3 | *Default:* |
| **comment** CommentEvent  Private    «Act» | Contains all l comments regarding the allergy event that were not captured in the Clinical Document process. | *Default:* |
| **dataEnterer** DataEnterer  Private    «Participation» | "A person entering the data into the originating system. The data entry person is collected optionally for internal quality control purposes. This includes the transcriptionist for dictated text." - HL7 V3 | *Default:* |
| **informationReporter** InformationReporter  Private | The person who reported information on the patient's behalf. This may be the patient him/herself. | *Default:* |
| **relatedIntoleranceCondition** RelatedIntoleranceCondition  Private    «ActRelationship» |  | *Default:* |
| **verifier** Verifier  Private    «Participation» |  | *Default:* |

##### IntoleranceConditionList

Type: **Class**

Status: Proposed. Version 1.0. Phase 1.0.

Package: Allergies Keywords:

Detail: *Created on* *11/6/2013*. *Last modified on 11/8/2013*.

GUID: {28D44057-4DD4-4f71-8F32-4DC520E7AF2C}

| Custom Properties | |
| --- | --- |
|  | isActive = False |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| Aggregation  Source -> Destination | Public intoleranceConditionEntry  IntoleranceConditionEntry | Public  IntoleranceConditionList |  |
| Association  Source -> Destination | Public  IntoleranceConditionList | Public patient  Patient |  |

Attributes

| **Attribute** | **Notes** | **Constraints and tags** |
| --- | --- | --- |
| **intoleranceConditionEntry** intoleranceConditionEntry  Private    «Observation» |  | *Default:* |
| **patient** Patient  Private |  | *Default:* |

##### NoKnownAllergyEntry

Type: **Class** IntoleranceConditionEntry

Status: Proposed. Version 1.0. Phase 1.0.

Package: Allergies Keywords:

Detail: *Created on* *11/6/2013*. *Last modified on 11/17/2013*.

GUID: {B7AB44B0-0FF7-4d3d-A54C-F19521F945D4}

| Custom Properties | |
| --- | --- |
|  | isActive = False |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| Generalization  Source -> Destination | Public  NoKnownAllergyEntry | Public  IntoleranceConditionEntry |  |
| NoteLink  Source -> Destination | Public  <anonymous> | Public  NoKnownAllergyEntry |  |

##### RelatedIntoleranceCondition

Type: **Class**

Status: Proposed. Version 1.0. Phase 1.0.

Package: Allergies Keywords:

Detail: *Created on* *11/6/2013*. *Last modified on 11/8/2013*.

GUID: {4CCDA014-61F1-4ff7-804F-5D85764FAE85}

| Custom Properties | |
| --- | --- |
|  | isActive = False |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| Association  Source -> Destination | Public RelatedIntoleranceCategory  IntoleranceConditionEntry | Public  RelatedIntoleranceCondition |  |
| Association  Source -> Destination | Public  RelatedIntoleranceCondition | Public IntoleranceConditionEntry  IntoleranceConditionEntry |  |

Attributes

| **Attribute** | **Notes** | **Constraints and tags** |
| --- | --- | --- |
| **RelatedIntoleranceCategory** Code  Public    «CS» | Indicates how the "Related Intolerance Condition" is related to the original "Intolerance Condition". Examples include "replaces", "replaced by", "parent", "child", etc. | *Default:* |
| **IntoleranceConditionEntry**  IntoleranceConditionEntry  Private    «Observation» |  | *Default:* |

#### Common

Type: Package

Status: Proposed. Version 1.0. Phase 1.0.

Package: FHIM

Detail: *Created on 11/6/2013*. *Last modified on 11/6/2013*

GUID: {2BB1F6A4-761B-44f3-9DD2-55F8AD7D189E}

**Common** - *(Class diagram)*

Created By: Protege User *on* 11/6/2013

Last Modified: 11/8/2013

Version: 1.0. *Locked:* False

GUID: {9E3A4FAA-9B44-4abf-B4BD-796195046658}



Figure: 11

##### Author

Type: **Class**

Status: Proposed. Version 1.0. Phase 1.0.

Package: Common Keywords:

Detail: *Created on* *11/6/2013*. *Last modified on 11/8/2013*.

GUID: {3F00AB18-C916-4867-B6C0-4AA7F524EC8B}

| Custom Properties | |
| --- | --- |
|  | isActive = False |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| Association  Source -> Destination | Public author  IntoleranceCondition | Public  Author |  |

Attributes

| **Attribute** | **Notes** | **Constraints and tags** |
| --- | --- | --- |
| **author**  Private |  | *Default:* |

##### CommentEvent

Type: **Class**

Status: Proposed. Version 1.0. Phase 1.0.

Package: Common Keywords:

Detail: *Created on* *11/6/2013*. *Last modified on 11/8/2013*.

GUID: {3E3C1ED2-F04F-4e17-9A6B-F9FCE0211418}

| Custom Properties | |
| --- | --- |
|  | isActive = False |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| Association  Source -> Destination | Public comment  IntoleranceConditionEntry | Public  CommentEvent |  |
| Association  Source -> Destination | Public  CommentEvent | Public author  IndividualProvider |  |

Attributes

| **Attribute** | **Notes** | **Constraints and tags** |
| --- | --- | --- |
| **id** Id  Public |  | *Default:* |
| **dateTime** PointInTime  Public |  | *Default:* |
| **comment** string  Public | Common  Class CommentEvent  This class is used to capture remarks about an Activity which might be made by various practitioners during the course of that Activity.  Note that this class used to contain an optional property called commentCategory, which was intended to provide an categorization of the comment for grouping purposes or to identify the situation in which the comment occured. The FHIM terminology team decided to remove this property in January 2013 as no values could be identified for the comment category. This property may be reinstated in the future should a desired set of categories be identified. | *Default:* |
| **author** IndividualProvider  Private    «Role» |  | *Default:* |

##### DataEntrer

Type: **Class**

Status: Proposed. Version 1.0. Phase 1.0.

Package: Common Keywords:

Detail: *Created on* *11/6/2013*. *Last modified on 11/8/2013*.

GUID: {0A074CCB-010B-4489-9219-A5A381863BF5}

| Custom Properties | |
| --- | --- |
|  | isActive = False |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| Association  Source -> Destination | Public dataEnterer  IntoleranceCondition | Public  DataEntrer |  |

Attributes

| **Attribute** | **Notes** | **Constraints and tags** |
| --- | --- | --- |
| **dataEnterer**  Public |  | *Default:* |

##### Verifier

Type: **Class**

Status: Proposed. Version 1.0. Phase 1.0.

Package: Common Keywords:

Detail: *Created on* *11/6/2013*. *Last modified on 11/20/2013*.

GUID: {0D163A26-5ACB-4504-99A7-887BCDA40B15}

| Custom Properties | |
| --- | --- |
|  | isActive = False |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| Association  Source -> Destination | Public  IntoleranceCondition | Public verifier  Verifier |  |

Attributes

| **Attribute** | **Notes** | **Constraints and tags** |
| --- | --- | --- |
| **verifier**  Public |  | *Default:* |

#### CommonProduct

Type: Package

Status: Proposed. Version 1.0. Phase 1.0.

Package: FHIM

Detail: *Created on 11/7/2013*. *Last modified on 11/7/2013*

GUID: {1EDCC169-4B58-47f0-BA9C-C91ABFFB97B7}

**CommonProduct** - *(Class diagram)*

Created By: Protege User *on* 11/7/2013

Last Modified: 11/7/2013

Version: 1.0. *Locked:* False

GUID: {A400F5B0-10B0-4eba-9F3D-7AB79461D952}



Figure: 12

##### MedicinalProduct

Type: **Class**

Status: Proposed. Version 1.0. Phase 1.0.

Package: CommonProduct Keywords:

Detail: *Created on* *11/7/2013*. *Last modified on 11/7/2013*.

GUID: {542AAAD8-2FC8-4bf3-8BB2-D90C690BA726}

| Custom Properties | |
| --- | --- |
|  | isActive = False |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| Association  Source -> Destination | Public  ConcommittantDrugs | Public medicinalProduct  MedicinalProduct |  |
| Association  Source -> Destination | Public  SuspectedAgent | Public medicinalProduct  MedicinalProduct |  |

Attributes

| **Attribute** | **Notes** | **Constraints and tags** |
| --- | --- | --- |
| **auxillaryLabel** String  Public | Contains remarks to personnel handling the medication. Examples include: Do not freeze, Keep refrigerated, Do not use after [a certain] date, Do not take if pregnant. | *Default:* |
| **brandName** Code  Private | “The name of the product kind described. If this is a specific manufactured (brand) product, this would be the proprietary name. For general product class descriptions this would be a non-proprietary name. This attribute may sometimes be used instead of a code and descriptive data elements when no suitable coding system is available. The data type for the name allows for suffixes and also other name parts, which might hold proprietary dose form (e.g., "capsil", "discus", "injection system") or other name parts which may be required for recognition of the product among health professionals. Note that these name parts are never to be used instead of proper descriptive data elements (formCode, ingredients and their quantities, etc.).” - HL7 Version 3 (ManufacturedMaterial.name). | *Default:* |
| **controlledSubstanceSchedule** Code  Private | “The name of the product kind described. If this is a specific manufactured (brand) product, this would be the proprietary name. For general product class descriptions this would be a non-proprietary name. This attribute may sometimes be used instead of a code and descriptive data elements when no suitable coding system is available. The data type for the name allows for suffixes and also other name parts, which might hold proprietary dose form (e.g., "capsil", "discus", "injection system") or other name parts which may be required for recognition of the product among health professionals. Note that these name parts are never to be used instead of proper descriptive data elements (formCode, ingredients and their quantities, etc.).” - HL7 Version 3 (ManufacturedMaterial.name). | *Default:* |
| **drugClass** DrugClass  Public    «ManufacturedMaterial» |  | *Default:* |
| **genericMedicine** GenericMedicine  Public    «ManufacturedMaterial» | "The non-proprietary, generic substance as which the same medicines is known in the literature independent of a specific manufacturer." - HL7 V3 | *Default:* |
| **ingrediant** DrugIngrediant  Public    «Role» | "Relates a product (typically a medicine) to a substance which it contains as an ingredient." - HL7 Version 3. | *Default:* |
| **investigationalNewDrugId** Code  Public | "Relates a product (typically a medicine) to a substance which it contains as an ingredient." - HL7 Version 3. | *Default:* |
| **isOverTheCounter** boolean  Public | Indicates whether this medication is sold over the counter. | *Default:* |
| **newDrugApplicationId** Code  Private | The unique identifier for the manufacturer's new drug application for this medicine. | *Default:* |
| **packagedMedicinalProduct** PackagedMedicinalProduct  Private    «Container» |  | *Default:* |

#### Person

Type: Package

Status: Proposed. Version 1.0. Phase 1.0.

Package: FHIM

Detail: *Created on 11/6/2013*. *Last modified on 11/6/2013*

GUID: {81CCB79B-D4FC-4851-B8AC-D6CC0013E49E}

**Person** - *(Class diagram)*

Created By: Protege User *on* 11/6/2013

Last Modified: 11/6/2013

Version: 1.0. *Locked:* False

GUID: {84B0AFE7-AC2F-4b22-B10C-35C04EAA2009}



Figure: 13

##### Patient

Type: **Class**

Status: Proposed. Version 1.0. Phase 1.0.

Package: Person Keywords:

Detail: *Created on* *11/6/2013*. *Last modified on 11/8/2013*.

GUID: {728502DB-7C34-4f77-86CE-A8B55C982645}

| Custom Properties | |
| --- | --- |
|  | isActive = False |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| Association  Source -> Destination | Public  IntoleranceConditionList | Public patient  Patient |  |

Attributes

| **Attribute** | **Notes** | **Constraints and tags** |
| --- | --- | --- |
| **beginDate** PointInTime  Public |  | *Default:* |
| **endDate** PointInTime  Public |  | *Default:* |
| **patientId** Id  Public |  | *Default:* |
| **status** Code  Public    «ValueSetConstraint» |  | *Default:* |

##### Patient

Type: **Class**

Status: Proposed. Version 1.0. Phase 1.0.

Package: Person Keywords:

Detail: *Created on* *11/6/2013*. *Last modified on 11/6/2013*.

GUID: {459CC8BC-1C23-4148-AAF0-B69C131A02B0}

| Custom Properties | |
| --- | --- |
|  | isActive = False |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| Generalization  Source -> Destination | Public  IndividualProvider | Public  Patient |  |

#### Provider

Type: Package

Status: Proposed. Version 1.0. Phase 1.0.

Package: FHIM

Detail: *Created on 11/6/2013*. *Last modified on 11/6/2013*

GUID: {EACC0EBE-85F1-4c17-BACC-22629AD9C433}

**Provider** - *(Class diagram)*

Created By: Protege User *on* 11/6/2013

Last Modified: 11/6/2013

Version: 1.0. *Locked:* False

GUID: {5CDD52E7-FD47-47ec-A98D-58D821EC5C1F}



Figure: 14

##### IndividualProvider

Type: **Class** Patient

Status: Proposed. Version 1.0. Phase 1.0.

Package: Provider Keywords:

Detail: *Created on* *11/6/2013*. *Last modified on 11/8/2013*.

GUID: {DBE97FA9-D464-4c98-9616-BD5C35ACAC1E}

Provider

Class IndividualProvider

A person who is authorized to provide health care services in the role of practitioner for a health care provider organization. The role of practitioner includes all functions performed for a health care provider organization in order to provide patient care and treatment.

| Custom Properties | |
| --- | --- |
|  | isActive = False |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| Generalization  Source -> Destination | Public  IndividualProvider | Public  Patient |  |
| Association  Source -> Destination | Public  ReactionObservation | Public author  IndividualProvider |  |
| Association  Source -> Destination | Public  CommentEvent | Public author  IndividualProvider |  |
| Association  Source -> Destination | Public  AdverseReactionReportingEvent | Public  IndividualProvider |  |

Attributes

| **Attribute** | **Notes** | **Constraints and tags** |
| --- | --- | --- |
| **signatureBlockName** PersonName  Public | Public «PN» PersonName signatureBlockName  Contains the name and title of the Practitioner as they wish it to be displayed with the notation that they signed the document electronically. For example, a practitioner who routinely uses a nickname for most correspondence would likely want their legal name on the signature block. In addition, this property would contain the title that they would use when electronically signing a document. For example, a practitioner may hold multiple titles, but would choose one to be used for signing. Examples of titles are Chief of Surgery, Dietician, Clinical Pharmacist, etc. | *Default:* |
| **MobilePhone** Telecommunications  Public | Public «TEL» Telecommunications mobilePhone  A telecommunication device that moves and stays with its owner. Suitable for urgent matters, the mobile phone is not the first choice for routine business. | *Default:* |
| **pager** Telecommunications  Public | Public «TEL» Telecommunications pager  A paging device suitable to solicit a callback or to leave a very short message. | *Default:* |

##### ServiceDeliveryLocation

Type: **Class**

Status: Proposed. Version 1.0. Phase 1.0.

Package: Provider Keywords:

Detail: *Created on* *11/6/2013*. *Last modified on 11/8/2013*.

GUID: {001DBBFE-574A-4588-B3E9-50F3D5507B5D}

Provider

Class ServiceDeliveryLocation

"The location to which the patient is assigned. It is a role played by a place at which services may be provided. Note that a single physical place can play multiple service delivery location roles each with its own attributes. For example, a Podiatry clinic and Research clinic may meet on alternate days in the same physical location; each clinic uses its own mailing address and telephone number." - HL7 V3.

| Custom Properties | |
| --- | --- |
|  | isActive = False |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| Association  Source -> Destination | Public  IntoleranceConditionEntry | Public serviceDeliveryLocation  ServiceDeliveryLocation |  |

Attributes

| **Attribute** | **Notes** | **Constraints and tags** |
| --- | --- | --- |
| **id** Id  Public    «II» | A unique string or token used to identify the Organization - Location combination. | *Default:* |
| **locationCategory** Code  Public    «CS» | "Code identifying the place where a drug or service is dispensed or administered." - NCPDP Telecommunication (Field 3Ø7-C7, Data Dictionary 201104). Use CMS's Place of Service Codes for Professional Claims. | *Default:* |
| **location** Location  Private    «Place» |  | *Default:* |
| **name** String  Public | The name of the Organization-Location. | *Default:* |
| **address** Address  Public | The business address of the Organization-Location.  "Specifies the address of the location where the drug or treatment was administered." - HL7 Version 2.8, RXA-28 | *Default:* |
| **email** Telecommunications  Public    «Tel» | The email address that a person uses while at their place of business. First choice for business related contacts during business hours.  Note that in HL7, the Telecommunications datatype contains a type code to indicate what kind of telecommunications address that is being referenced. The FHIM explicitly models the telecommuncations type, so in this case the attribute name is "Work Email", and the type code would be set to "workplace" when targeting an HL7 implementation.  "Contains the patient's personal telecommunication contact information." - HL7 Version 2.8, PID-40. | *Default:* |
| **phone** Telecommunications  Public    «Tel» | The business phone number of the Organization-Location. | *Default:* |
| **organization** Organization  Private    «Organization» | Points to the Organization operating at the Location. | *Default:* |

#### Public HealthReporting

Type: Package

Status: Proposed. Version 1.0. Phase 1.0.

Package: FHIM

Detail: *Created on 11/7/2013*. *Last modified on 11/7/2013*

GUID: {1A65008B-761D-478c-A976-6F5B8334969A}

**Public HealthReporting** - *(Class diagram)*

Created By: Protege User *on* 11/7/2013

Last Modified: 11/7/2013

Version: 1.0. *Locked:* False

GUID: {58B75BD2-EECE-498f-93C7-05746C95760B}



Figure: 15

##### NotificationReport

Type: **Class**

Status: Proposed. Version 1.0. Phase 1.0.

Package: Public HealthReporting Keywords:

Detail: *Created on* *11/7/2013*. *Last modified on 11/7/2013*.

GUID: {193EAA1E-0A09-48d6-BC58-788F57F16ABA}

| Custom Properties | |
| --- | --- |
|  | isActive = False |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| Generalization  Source -> Destination | Public  AdverseReactionReportingEvent | Public  NotificationReport |  |

Attributes

| **Attribute** | **Notes** | **Constraints and tags** |
| --- | --- | --- |
| **alertDateTime** PointInTime  Public    «TS» |  | *Default:* |
| **CareGiver** IndividualProvider  Public    «Role» | Identifies the person who provided care for the subject of the report. | *Default:* |
| **encounterEvent** EncounterEvent  Public    «PatientEncounter» |  | *Default:* |
| **exposure** Exposure  Public    «Act» |  | *Default:* |
| **height** \_VitalSignObservationEvent  Public    «Observation» |  | *Default:* |
| **labTestPromise** LabTestPromise  Public    «EntryPoint» |  | *Default:* |
| **medicationHistory** MedicationListory  Public    «Act» |  | *Default:* |
| **moreInformationlProvider** IndividualProvider  Public    «Role» | This information relates to the current or past provider information that may be contacted for additional follow up information. The HCP may or may not be the report sender or primary source reporter | *Default:* |
| **pregnancyMenstrualStatus** PregnancyMenstrualStatus  Public    «Observation» |  | *Default:* |
| **reportCategory** NotificationReportCategory  Public |  | *Default:* |
| **reportCreatedBy** HealthcareProvider  Public    «Role» |  | *Default:* |
| **reportDateTime** PointInTime  Public | Date and time the report is being sent to public health agencies. | *Default:* |
| **reportId** Id  Public    «II» |  | *Default:* |
| **reportingSystem** String  Public |  | *Default:* |
| **reportSentBy** HealthcareProvider  Public    «Role» |  | *Default:* |
| **reportSentTo** Organization  Public    «Organization» |  | *Default:* |
| **reportSubject** Patient  Public    «Patient» |  | *Default:* |
| **sendingSystem** String  Public |  | *Default:* |
| **serviceDeliveryLocation** ServiceDeliveryLocation  Private    «Role» |  | *Default:* |
| **status** Code  Private    «CS» |  | *Default:* |
| **vitalSignObservationEvent** \_VitalSignObservationEvent  Public    «Observation» |  | *Default:* |
| **weight** VitalSignObservationEvent  Private    «Observation» |  | *Default:* |

### Allergy, Intolerance and Adverse Reaction Class

Type: Package

Status: Proposed. Version 1.0. Phase 1.0.

Package: Nov 2013 Prototype CP.6.2 Immunization Management Interoperability Specification

Detail: *Created on 11/4/2013*. *Last modified on 11/4/2013*

GUID: {A06532C1-CBF1-40ff-A171-492C7FE2362B}

**Allergy, Intolerance and Adverse Reaction Class** - *(Class diagram)*

Created By: Steve Hufnagel *on* 11/4/2013

Last Modified: 11/4/2013

Version: 1.0. *Locked:* False

GUID: {78EB0EAF-C301-4955-BBA6-591613AC7EE5}



Figure: 16

#### Allergy, Intolerance and Adverse Reaction

Type: **Class** Observation

Status: Proposed. Version 1.0. Phase 1.0.

Package: Allergy, Intolerance and Adverse Reaction Class Keywords:

Detail: *Created on* *1/22/2012*. *Last modified on 11/20/2013*.

GUID: {AD9BD988-9F66-4f83-BD74-4F975729FF5C}

Adverse Reaction is a specific reactions to a substance. [FHIR]

**Resource AllergyIntolerance** - [FHIR]

Allergy/Intolerance resources are used to provide information about adverse sensitivities to substances that lead to physiologic changes that are clinically observable. An adverse sensitivity is defined as:

A condition expected to result in undesirable physiologic reaction to an amount of a substance that would not produce a reaction in most individuals. The substance is the trigger of an immunologic response that produces the observed physiologic changes, or in some instances nonimmunologic mechanisms that produce clinically identical physiologic changes. The immunologic response might be considered the actual cause of the reaction, but it is exposure to the trigger substance that is clinically observable.

This definition excludes clinically identical episodes that may be caused by physical agents, such as heat, cold, sunlight, or vibration, by exercise activity, or by infectious agents. Those conditions caused by physical agents or infectious would be captured on the problem list (List/Condition Resources). The allergy/intolerance list is a list of conditions that represent a propensity unique to this individual for a reaction upon future exposure to a specified substance.

Note that this specification draws a distinction between the patients condition/problem list and an allergy/intolerance list, even though allergies and intolerances are also conditions. This is because the distinction is a long established clinical workflow, even to patients. Asking an individual "if they have any problems" is not going to invoke an account of their past reactions to medications or foods. Instead, they are asked if they "have any allergies". An allergy/intolerance is also different in that a potential harm from exposure to an external substance that may be ordered by a provider in the course of their care but is not inherent to exposure to that substance for the general population.

Most of the details of the sensitivity can be found in the set of reactions that are associated with the resource, though these may not be present when the patient has not provided enough information. Adverse Reactions do not have to be always associated with an AllergyIntolerance which may appropriate when an single reaction has not provided enough evidence for a meaningful Allergy/Intolerance, or in specific views of events rather than in a general clinical record.

**Criticality vs Severity**

Criticality is defined as "The potential seriousness of 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 allergic condition, not the reaction(s).

High criticality does not equate to a future severe reaction, but rather the potential for a severe and life-threatening reaction. Most reaction types are dose dependent, including anaphylaxis. Therefore, although they have a sensitivity of high criticality, exposure to a small dose of the substance to which they are sensitive might result in only a mild reaction. Severity of the reaction is also dependent on the route of exposure, but criticality since it applies to the condition, is not.

| Responsibilities (external requirements) | |
| --- | --- |
|  | CP.1.2#01 The system SHALL provide the ability to manage true allergy, intolerance, and adverse reaction to drug, food or environmental triggers as unique, discrete entries. *(Proposed, Medium difficulty)* |
|  | CP.1.2#02 The system SHOULD provide the ability to manage the reason for entry or maintenance (including update or remove) of the allergy, intolerance or adverse reaction. *(Proposed, Medium difficulty)* |
|  | CP.1.2#03 The system SHALL provide the ability to manage the reaction type as discrete data. *(Proposed, Medium difficulty)* |
|  | CP.1.2#04 The system SHALL provide the ability to manage the severity of an allergic or adverse reaction as discrete data. *(Proposed, Medium difficulty)* |
|  | CP.1.2#07 The system SHOULD provide the ability to manage the source of allergy, intolerance, and adverse reaction information. *(Proposed, Medium difficulty)* |
|  | CP.1.2#13 The system SHALL provide the ability to tag that the list of medications and other agents has been reviewed. *(Proposed, Medium difficulty)* |
|  | CP.1.2#16 The system SHOULD provide the ability to manage allergy information as coded data. *(Proposed, Medium difficulty)* |
|  | CP.1.2#17 The system SHOULD provide the ability to capture and maintain the required documentation of allergies prior to completion of the medication order. *(Proposed, Medium difficulty)* |
|  | CP.1.2#18 The system SHOULD provide the ability to capture and render that the allergies are “Unknown” or “Unable to Assess Allergies". *(Proposed, Medium difficulty)* |
|  | CP.1.2#19 The system SHOULD provide the ability to capture the reason for “Unknown” or “Unable to Assess Allergies” documentation. *(Proposed, Medium difficulty)* |
|  | CP.1.2#21 The system SHOULD provide the ability to capture free text allergies and render them in a manner that distinguishes them from coded allergy entries. *(Proposed, Medium difficulty)* |
|  | CP.1.2#22 The system SHOULD tag and render an indicator that interaction checking will not occur against free text allergies. *(Proposed, Medium difficulty)* |
|  | CP.1.2#24 The system SHOULD provide the ability to link allergic reactions to specific treatment or diagnostic protocols. *(Proposed, Medium difficulty)* |
|  | CP.1.2#25 The system SHOULD conform to function CPS.4.2.1 (Support for Medication Interaction and Allergy Checking) to render any potential interactions when capturing or maintaining allergies, intolerances or adverse reactions. *(Proposed, Medium difficulty)* |
|  | CP.1.2#26 The system SHOULD capture information that a provider was presented with and acknowledged a drug interaction notification. *(Proposed, Medium difficulty)* |
|  | CP.6.2#04 The system SHOULD provide the ability to capture, in a discrete field, an allergy/adverse reaction to a specific unization. *(Proposed, Medium difficulty)*  IS: CP.6.2#04 The system SHOULD provide the ability to capture, in a discrete field, an allergy/adverse reaction to a specific **imm**unization.  SB: CP.6.2#04 The system SHOULD provide the ability to capture, in a discrete field, an allergy/adverse reaction to a specific **im**munization. |
|  | CP.6.2#09 The system SHALL conform to function CP.1.2 (Manage Allergy, Intolerance and Adverse Reaction List). *(Proposed, Medium difficulty)* |

| Custom Properties | |
| --- | --- |
|  | isActive = False |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| Realization  Source -> Destination | Public  Allergy, Intolerance and Adverse Reaction | Public  CP.6.2#04 The system SHOULD provide the ability to capture, in a discrete field, an allergy/adverse reaction to a specific unization. |  |
| Realization  Source -> Destination | Public  Allergy, Intolerance and Adverse Reaction | Public  CP.6.2#09 The system SHALL conform to function CP.1.2 (Manage Allergy, Intolerance and Adverse Reaction List). |  |
| Realization  Source -> Destination | Public  Allergy, Intolerance and Adverse Reaction | Public  CP.1.2#01 The system SHALL provide the ability to manage true allergy, intolerance, and adverse reaction to drug, food or environmental triggers as unique, discrete entries. |  |
| Realization  Source -> Destination | Public  Allergy, Intolerance and Adverse Reaction | Public  CP.1.2#02 The system SHOULD provide the ability to manage the reason for entry or maintenance (including update or remove) of the allergy, intolerance or adverse reaction. |  |
| Realization  Source -> Destination | Public  Allergy, Intolerance and Adverse Reaction | Public  CP.1.2#03 The system SHALL provide the ability to manage the reaction type as discrete data. |  |
| Realization  Source -> Destination | Public  Allergy, Intolerance and Adverse Reaction | Public  CP.1.2#04 The system SHALL provide the ability to manage the severity of an allergic or adverse reaction as discrete data. |  |
| Realization  Source -> Destination | Public  Allergy, Intolerance and Adverse Reaction | Public  CP.1.2#16 The system SHOULD provide the ability to manage allergy information as coded data. |  |
| Realization  Source -> Destination | Public  Allergy, Intolerance and Adverse Reaction | Public  CP.1.2#17 The system SHOULD provide the ability to capture and maintain the required documentation of allergies prior to completion of the medication order. |  |
| Realization  Source -> Destination | Public  Allergy, Intolerance and Adverse Reaction | Public  CP.1.2#19 The system SHOULD provide the ability to capture the reason for “Unknown” or “Unable to Assess Allergies” documentation. |  |
| Realization  Source -> Destination | Public  Allergy, Intolerance and Adverse Reaction | Public  CP.1.2#21 The system SHOULD provide the ability to capture free text allergies and render them in a manner that distinguishes them from coded allergy entries. |  |
| Realization  Source -> Destination | Public  Allergy, Intolerance and Adverse Reaction | Public  CP.1.2#26 The system SHOULD capture information that a provider was presented with and acknowledged a drug interaction notification. |  |
| Realization  Source -> Destination | Public  Allergy, Intolerance and Adverse Reaction | Public  CP.1.2#24 The system SHOULD provide the ability to link allergic reactions to specific treatment or diagnostic protocols. |  |
| Realization  Source -> Destination | Public  Allergy, Intolerance and Adverse Reaction | Public  CP.1.2#25 The system SHOULD conform to function CPS.4.2.1 (Support for Medication Interaction and Allergy Checking) to render any potential interactions when capturing or maintaining allergies, intolerances or adverse reactions. |  |
| Realization  Source -> Destination | Public  Allergy, Intolerance and Adverse Reaction | Public  CP.1.2#13 The system SHALL provide the ability to tag that the list of medications and other agents has been reviewed. |  |
| Dependency  Source -> Destination | Public  Manage Allergen & Adverse Reaction Events | Public  Allergy, Intolerance and Adverse Reaction |  |
| Association  Unspecified | Public  Allergy, Intolerance and Adverse Reaction type Enumeration | Public  Allergy, Intolerance and Adverse Reaction |  |
| Generalization  Source -> Destination | Public  Allergy, Intolerance and Adverse Reaction | Public  Observation |  |
| Dependency  Source -> Destination | Public  CPS.4.2.1 Support for Medication Interaction and Allergy Checking | Public  Allergy, Intolerance and Adverse Reaction |  |
| Realization  Source -> Destination | Public  Allergy, Intolerance and Adverse Reaction | Public  CP.1.2#18 The system SHOULD provide the ability to capture and render that the allergies are “Unknown” or “Unable to Assess Allergies". |  |
| Realization  Source -> Destination | Public  Allergy, Intolerance and Adverse Reaction | Public  CP.1.2#07 The system SHOULD provide the ability to manage the source of allergy, intolerance, and adverse reaction information. |  |
| Realization  Source -> Destination | Public  Allergy, Intolerance and Adverse Reaction | Public  CP.1.2#22 The system SHOULD tag and render an indicator that interaction checking will not occur against free text allergies. |  |
| Realization  Source -> Destination | Public  Allergy, Intolerance and Adverse Reaction | Public  CP.6.2 Manage Immunization Administration |  |
| Dependency depends on  Source -> Destination | Public  Allergy, Intolerance and Adverse Reaction | Public  CP.1.2 Manage Allergy, Intolerance and Adverse Reaction List |  |
| Realization realize  Source -> Destination | Public  AdverseReaction | Public  Allergy, Intolerance and Adverse Reaction |  |
| Realization realize  Source -> Destination | Public  AllergyIntolerance | Public  Allergy, Intolerance and Adverse Reaction |  |

Attributes

| **Attribute** | **Notes** | **Constraints and tags** |
| --- | --- | --- |
| **data of review**  Public |  | *Default:* |
| **Patient** link  Public |  | *Default:* |
| **reaction type**  Public | CP.1.2#03 The system SHALL provide the ability to manage the reaction type as discrete data. | *Default:* |
| **severity**  Public |  | *Default:* |
| **type**  Public |  | *Default:* |
| **source**  Public | CP.1.2#07 The system SHOULD provide the ability to manage the source of allergy, intolerance, and adverse reaction information. | *Default:* |

Operations

| **Method** | **Notes** | **Parameters** |
| --- | --- | --- |
| **capture()**  Public «SHALL» | CP.1.2#01 The system SHALL provide the ability to manage true allergy, intolerance, and adverse reaction to drug, food or environmental triggers as unique, discrete entries.  CP.1.2#07 The system SHOULD provide the ability to manage the source of allergy, intolerance, and adverse reaction information.  CP.1.2#19 The system SHOULD provide the ability to capture the reason for “Unknown” or “Unable to Assess Allergies” documentation.  CP.1.2#13 The system SHALL provide the ability to tag that the list of medications and other agents has been reviewed.  CP.1.2#21 The system SHOULD provide the ability to capture free text allergies and render them in a manner that distinguishes them from coded allergy entries.  CP.1.2#16 The system SHOULD provide the ability to manage allergy information as coded data.  CP.1.2#22 The system SHOULD tag and render an indicator that interaction checking will not occur against free text allergies. |  |

#### Allergy, Intolerance and Adverse Reaction type Enumeration

Type: **Class**

Status: Proposed. Version 1.0. Phase 1.0.

Package: Allergy, Intolerance and Adverse Reaction Class Keywords:

Detail: *Created on* *1/22/2012*. *Last modified on 11/4/2013*.

GUID: {4A1A4ED8-04A6-4688-8DB2-F2F50E47C3CD}

| Responsibilities (external requirements) | |
| --- | --- |
|  | CP.1.2#18 The system SHOULD provide the ability to capture and render that the allergies are “Unknown” or “Unable to Assess Allergies". *(Proposed, Medium difficulty)* |

| Custom Properties | |
| --- | --- |
|  | isActive = False |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| Association  Unspecified | Public  Allergy, Intolerance and Adverse Reaction type Enumeration | Public  Allergy, Intolerance and Adverse Reaction |  |
| Association  Source -> Destination | Public  Order for Medication | Public  Allergy, Intolerance and Adverse Reaction type Enumeration |  |
| Realization  Source -> Destination | Public  Allergy, Intolerance and Adverse Reaction type Enumeration | Public  CP.1.2#18 The system SHOULD provide the ability to capture and render that the allergies are “Unknown” or “Unable to Assess Allergies". |  |

Attributes

| **Attribute** | **Notes** | **Constraints and tags** |
| --- | --- | --- |
| **adverse reaction**  Private |  | *Default:* |
| **allergy**  Private |  | *Default:* |
| **intolerance**  Private |  | *Default:* |
| **No Known Allergies (NKA)**  Private | CP.1.2#18 The system SHOULD provide the ability to capture and render that the allergies are “Unknown” or “Unable to Assess Allergies".  CP.1.2#19 The system SHOULD provide the ability to capture the reason for “Unknown” or “Unable to Assess Allergies” documentation. | *Default:* |
| **No Known Drug Allergies (NKDA)**  Private | CP.1.2#19 The system SHOULD provide the ability to capture the reason for “Unknown” or “Unable to Assess Allergies” documentation. | *Default:* |
| **unable to assess**  Private | CP.1.2#18 The system SHOULD provide the ability to capture and render that the allergies are “Unknown” or “Unable to Assess Allergies". | *Default:* |
| **unknown**  Private |  | *Default:* |

#### Allergy, Intolerance and Adverse Reactions

Type: **Class** Observations

Status: Proposed. Version 1.0. Phase 1.0.

Package: Allergy, Intolerance and Adverse Reaction Class Keywords:

Detail: *Created on* *1/22/2012*. *Last modified on 11/20/2013*.

GUID: {1D293F34-9B79-4226-99DB-7E73ACDFE388}

| Custom Properties | |
| --- | --- |
|  | isActive = False |

*Connections*

| **Connector** | **Source** | **Target** | **Notes** |
| --- | --- | --- | --- |
| Generalization  Source -> Destination | Public  Allergy, Intolerance and Adverse Reactions | Public  Observations |  |
| Realization  Source -> Destination | Public  CP.1.2#05 The system SHALL provide the ability to manage a report of No Known Allergies (NKA) for the patient. | Public  Allergy, Intolerance and Adverse Reactions |  |
| Realization  Source -> Destination | Public  CP.1.2#06 The system SHALL provide the ability to manage a report of No Known Drug Allergies (NKDA) for the patient. | Public  Allergy, Intolerance and Adverse Reactions |  |
| Realization  Source -> Destination | Public  CP.1.2#08 The system SHALL provide the ability to tag as deactivated an allergy, intolerance or adverse reaction. | Public  Allergy, Intolerance and Adverse Reactions |  |
| Realization  Source -> Destination | Public  CP.1.2#09 The system SHALL provide the ability to capture as discrete data the reason for deactivation of an allergy, intolerance or adverse reaction. | Public  Allergy, Intolerance and Adverse Reactions |  |
| Realization  Source -> Destination | Public  CP.1.2#10 The system SHALL provide the ability to render allergies, intolerances and adverse reactions that have been deactivated. | Public  Allergy, Intolerance and Adverse Reactions |  |
| Realization  Source -> Destination | Public  CP.1.2#23 The system SHOULD provide the ability to render historical allergy information. | Public  Allergy, Intolerance and Adverse Reactions |  |

Operations

| **Method** | **Notes** | **Parameters** |
| --- | --- | --- |
| **manage()**  Public |  |  |