HL7 Version 3 Domain Analysis Model:
Allergies and Intolerances, Release 1
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Informative Ballot

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### Revision History

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Introduction

The Patient Care Allergy and Intolerance Project began in 2010 following the initial release of meaningful use standards in the United States. While medication allergies were included in these US standards, no standards were included for other allergies related to food, the environment, vaccines or implantable devices. Earlier work of the HL7 Patient Care Work Group revealed a V3 DSTU RMIM, balloted in 2007, which remained untested. This Domain Analysis Model reflects the efforts of the Patient Care Work Group along with the sponsorship of other HL7 workgroups (Pharmacy, EHR, Decision Support Systems, and Orders and Observations) to develop an approach for documenting and exchanging allergy and intolerance data within the institutional health care record, and propose a model for interoperability to other providers and documentation systems such as the PHR.

To that end, the scope of this Domain Analysis Model is broad, and is intended to unify a number of international models designed to deal with the documentation and interoperability of allergy and intolerance conditions. The use cases and models were developed with two goals in mind. The first goal was to provide the reader examples of the following concepts:

- Documentation of a newly observed vs. reported allergy or intolerance
- To establish that an allergy and intolerance (and a preference) should be treated as an adverse reaction until clearly differentiated (by test, or by clinical opinion)
- To delineate the difference between severity and criticality and how to apply these concepts to an adverse reaction vs. a condition
- To demonstrate the creation and maintenance of an allergy list, as well as identify how to update a list after misattribution, or ensure that some statement of assessment is included on the list (no known allergies, unable to determine).

The second goal of the project was to highlight the fact that allergies and intolerances are not just related to drugs but should include food, device and environmental allergies.

Ongoing work will include the identification of value sets and terminology code systems that support the interoperability of allergy and intolerance conditions, and in the future support clinical decision support systems. In addition, future work will include the mapping of this domain to the RIM.
Use Case 1: Observed New Allergy

Description:
The purpose of this case is to describe the observation of a new adverse reaction to a substance in the Emergency Room by a health care provider. The observation and clinical history allow the clinician to determine that there is a relationship between the substance and the reaction leading to diagnosis of an allergy. The allergy is then documented in the patient’s medical record.

Conditions:
- The patient receives care within a health system that exchanges data between providers and between provider institutions.

Exceptions: none

Preconditions:
- The patient has no known allergies or intolerances prior to this event.

Use Case Sequence Steps:
1. Ned Nuclear, a 7 year old boy, who brings his lunch to school, but trades lunches with a friend.
3. Ned starts complaining that the back of his throat itches, develops hives and he can’t swallow.
4. Ned’s friend alerts the lunchroom monitor and Ned is taken to the school nurse, Barbara Bandaid, who calls for an ambulance as well as Ned’s mother.
5. The ambulance starts treatment for supposed adverse reaction to food.
6. Upon arrival to the Emergency Room, Ned’s symptoms have diminished but the Emergency Room physician is able to observe evidence of the adverse reaction.
7. Ned is further treated in the Emergency Room.
8. The Emergency Room physician takes a history from Ned and his mother.
9. Based on the clinical history and the observation of symptoms the Emergency Room physician determines there is a relationship between the peanut butter sandwich and the subsequent adverse reaction.
10. The Emergency Room physician updates the medical record with the condition “allergic to peanuts”.

Post Conditions
None

Actors:
Family: Ned Nuclear (boy)
        Nelda Nuclear (mother)
Friend: Fred Friendly
Emergency Room Provider: Eric Emergency
Allergist: Ramsey Reaction
Registered Nurse: Nancy Nightingale
School Nurse: Barbara Bandaid

Use Case Scenario:

Ned Nuclear is in second grade at Happy Valley Elementary school. His mother, Nelda Nuclear, often packs his lunch as he is a picky eater. One day, his best friend Fred Friendly, asks to trade lunch with him. Ned agrees and starts to eat Fred’s peanut butter sandwich. After eating about half the sandwich, Ned starts complaining that his throat is itchy. Fred tells him to drink some milk and he’ll be fine. Ned starts to drink, but is having more difficulty with talking and swallowing. Fred calls over a lunchroom monitor who accompanies Ned and Fred to the school nurse, Barbara Bandaid.

Fred starts telling Nurse Bandaid what happened and Barbara quickly realizes that Ned needs immediate medical attention. She calls an ambulance and Mrs. Nuclear, Ned’s mother. Mrs. Nuclear agrees to meet the ambulance at the Emergency Room. When the ambulance arrives, Barbara Bandaid briefs the crew on Ned’s condition and Mrs. Nuclear’s permission to transport to the hospital.

Emergency Care: The ambulance takes Ned to the Emergency Department. On the way, they administered epinephrine and diphenhydramine and notify the emergency room of the peanut exposure in a previously healthy child without a documented food allergy. Ned is quickly taken to a room when he arrives and Mrs. Nuclear begins filling out paperwork and giving Ned’s medical history. Ned was examined by Eric Emergency and noted to have hives, swelling of eyes and lips and an itchy throat. Ned is then stabilized with additional epinephrine, diphenhydramine, corticosteroids, IV fluids, and oxygen.

Based on the clinical history and the observation of Ned’s symptoms, Eric Emergency the physician determines there is a relationship between the peanut butter sandwich and the subsequent adverse reaction. Ned remains in the emergency room for observation for several hours with his mother. Dr. Emergency reassures Mrs. Nuclear that Ned will be fine and that they should follow up with his pediatrician, Karen Kidder, in a couple of days.

Dr. Emergency records a new allergy on the patient’s medical record allergy and intolerance list. The new allergy is an observed allergic reaction to peanuts. Details include the severity of the reaction and the criticality of the condition based on the clinical assessment of Dr. Emergency.

Recommendations include a confirmation of the sensitivity to peanuts through a referral to an allergist.
Use Case 2: A New Reported Intolerance

Description:
A patient manifests an intolerance to lactose after a course of antibiotics.

Conditions:
- Patient had no previously documented food allergies or intolerances.

Exceptions: none

Use Case Sequence Steps:
1. The patient Eve Everywoman has just completed a course of Zythromax Z-Pack to treat an abscessed tooth. She has experienced nausea and diarrhea with the treatment.
2. Eve Everywoman makes an appointment to visit with her primary care provider Harold Hippocrates to address the continued nausea and diarrhea following the completion of the Zythromax treatment.
3. The patient tells her primary care provider that her symptoms seem to be exacerbated by milk and milk products.
4. The primary care provider completes his evaluation determining that the patient may have become lactose intolerant due to iatrogenic changes in her gut flora.
5. The primary care provider documents the potential new lactose intolerance in the medical record on the allergy and intolerance list.
6. The primary care provider orders a lactose tolerance test, which indicates an intolerance to lactose.
7. The primary care provider updates the medical record allergy and intolerance list with the verified lactose intolerance.

Post Condition
None

Actors:
Patient: Eve Everywoman
Primary Care Provider: Harold Hippocrates

Use Case Scenario:

Eve Everywoman is a 45 year old female with no known history of allergies or intolerances to medications or food. She started to experience a pain in her lower jaw when drinking cold beverages and that pain increased resulting in a visit to her dentist. An x-ray revealed an abscess required antibiotic therapy prior to performing a root canal. After beginning a three day course of Zythromax, Eve began to feel nauseous and had multiple episodes of diarrhea. After finishing the Zythromax, these symptoms continued. Eve then scheduled an appointment with her primary care provider Harold Hippocrates.

Harold Hippocrates documents the following clinical assessment:
Chief Complaint – nausea and diarrhea

Medical History – patient is hypertensive, and has a history of heart burn. Eve Everywoman states she has had nausea and diarrhea since taking the Zythromax, and her symptoms seem to be worse after meals, particularly when she drinks milk or eats milk-related products such as soft cheese.

Medications – completed three day course of Zythromax. Takes beta-blocker and diuretic each day. Takes a multi-vitamin daily.

Physical Examination – well nourished female with normal exam except noted bowel sounds. Patient has lost 4 pounds since her last check-up six months ago.

Diagnosis – potential lactose intolerance secondary to antibiotic use. Harold Hippocrates documents a new lactose intolerance in the medical record on the allergy and intolerance list.

Plan – Order a lactose tolerance test and to the dietitian for counseling on a low lactose diet.

Harold Hippocrates updates the lactose intolerance in the medical record on the allergy and intolerance list as verified by a lactose intolerance test.

Use Case 3: Adverse Reaction to Medications

Use Case Description

The purpose of this use case is to support the documentation of an adverse reaction to medications in a hospital clinical information system.

Primary Actor

ED attending physician - Eric Emergency
(Role: accessing EMR data; documenting medical history, clinical findings and allergy/intolerance and adverse reaction information; authoring of discharge summary; updating PHR contents where applicable)

Other Actors

Patient (subject of care and informant; updating PHR where appropriate) - Adam Everyman
Hospital EMR/CIS (clinical information and discharge summary repository; documentation and authoring applications)
Primary care physician/GP (patient nominated recipient of discharge summary information) - Patricia Primary
Community pharmacist (patient nominated recipient of medication allergy/intolerance and adverse reaction information) - Susan Script
PHR (clinical and patient entered information repository; query/retrieval and documentation)
applications) [in Australia, this will be PCEHR]

Assumptions
Hospital has EMR/CIS that:

- Provide access to Allergy/Intolerance and adverse reaction data
- Support documentation of allergy/intolerance and adverse reaction details
- Support generation and exchange of discharge summary/event summary containing allergy/intolerance and adverse reaction details; and adverse reactions details to be sent to nominated community pharmacist
- Updating PHR with recent adverse reaction details

Pre-conditions
Patient Adam Everyman presents to hospital with signs and symptoms of adverse reactions to medication(s).
The hospital uses electronic medical record systems supporting the documentation of the adverse reaction event, management and revision of allergy/intolerance list.
Receiving systems (e.g. Primary care provider, community pharmacist) capable of receiving allergy/intolerance and adverse reaction information.

Triggers
A patient suffering from an adverse reaction to prescribed medication presents at hospital/ED for treatment is assessed, diagnosed and treated for the adverse reaction.

Exclusions
Patient conditions which are not relevant to allergy/intolerance or adverse reaction topics

Use Case Sequence of Steps
1. Patient Adam Everyman presents to the Emergency Department with a skin rash.
2. Patient provides information on medical and medication histories which includes a recently added new medication by patient’s primary care provider.
3. The Emergency Department physician Eric Emergency accesses the hospital EMRS or CIS for the patient’s history/clinical information including allergy/intolerance and adverse reaction data.
4. The Emergency Department (ED) physician does not find any pre-existing allergy/intolerance information on this patient from available documentation.
5. The ED physician evaluates the clinical data that can be accessed through EMRS and takes full medical and medication histories.
6. The ED physician evaluates the patient’s condition, makes a diagnosis, and attributes the diagnosed condition to a probable case of hypersensitivity reaction to sulphonylurea (Glicazide) order and gives appropriate treatment.
7. ED physician documented in EMRS patient’s clinical details including presenting problem, medical history, medication history, treatment and outcomes.
8. ED physician updates allergy/intolerance list and medical alert on allergy/hypersensitivity to recently prescribed medication (Glicazide)

9. ED physician generates a discharge summary generated using the hospital clinical information system or EMRS for transmission to patient nominated primary care physician Patricia Primary. The discharge summary contains the allergy/intolerance list which include an entry of sulphonylurea/glicazide

10. ED physician enters adverse reactions details in EMRS allergy/intolerance list and for transmission to patient’s community pharmacist where applicable

11. ED physician updates PHR with relevant clinical details where appropriate (as consented by patient)

Post-conditions

1. Updated EMRS allergy/intolerance list with an entry of sulphonylurea / glicazide, adverse reactions details to sulphonylurea and medical alerts
2. Hospital discharge summary containing allergy/intolerance list and adverse reaction information on sulphonylurea and transmitted to patient’s primary care physician/GP
3. Allergy/intolerance and adverse reaction information also transmitted patient specified pharmacy(ies) and PHR where applicable
4. PHR updated with relevant clinical information including allergy/intolerance and adverse reaction information

Notes

Allergy/intolerance details captured and exchanged include:
medication class, medication name, dose, datetime of medication start, datetime of adverse reaction onset, adverse reaction details, datetime of presentation to hospital/ED, datetime of treatment and details, datetime of resolution, updated allergy/Intolerance list, informant/information provider (patient), author (may also be the attending physician)

Use Case Scenario

A 60-year old man Adam Everyman presents himself at the Emergency Department of a local hospital with an extensive skin rash. His presenting complaints include a rash starting on the back and palm of his hands spreading quickly to the arms, neck, face and trunk. The lesions consist of concentric rings of targetoid lesions with blistering appearing in some areas. Mucous membrane involvement also started with lesions appearing on his lips and inside his mouth.

Medical History:
Hypercholesterolemia diagnosed 15 years ago
Hypertension for 10 years
Chronic atrial fibrillation diagnosed 4 years ago
Type II diabetes diagnosed 2 years ago

Medications:
Simvastatin 20 mg at night
Rampil 10 mg once daily
Warfarin 4 mg once daily
Metformin 1000 mg twice daily
Glicazide 40 mg once daily in the morning (commenced 6 weeks ago after medication review by his primary care physician)
He denies taking any other medications including OTC or other non prescribed medications.

**Allergy/Intolerance List/Alert:**
Hospital EMRS does not have pre-existing allergy/intolerance information on patient

**Physical Examinations:**
Blood pressure: 135/80 mmHG
Heart: rate = 86/min, no murmur, no added HS; ECG = AF, no ischaemia
Respiratory, CNS, Abdomen/GI, Genito-urinary: NAD

**Blood Tests:**
BSL = 5.8 mmol/L
U+E = normal
LFT = normal

**Diagnosis:**
Patient is diagnosed by the ED physician to have suffered from erythema multiforme.
Given that patient was prescribed and commenced Glicazide, it is probable that this was a case of hypersensitivity reaction to sulphonylurea (Glicazide).

**Treatment:**
Patient is admitted into the medical unit of the hospital where his condition is managed in the general medicine clinical unit. The glicazide is stopped and symptomatic treatment includes oral antihistamines, analgesics, local skin care, and soothing mouthwashes

**Outcomes:**
The erythema multiforme resolved.
The adverse reaction to glicazide is documented in patient’s medical record.
The allergy/intolerance list is updated with inclusion of glicazide as a trigger to adverse reactions. On discharge, a discharge summary is generated with a summary of the reasons for encounter, treatment given, outcomes and revised allergy/intolerance list and clinical alert. A discharge summary with allergy/intolerance list and adverse reaction information on glicazide is transmitted to patient’s primary care physician
The allergy/intolerance list and adverse reaction information on glicazide is also transmitted to patient specified pharmacy(ies) and PHR.

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**References:**
Use Case 4: Creation and Maintenance of List of Allergic or Intolerance Conditions

Description
The purpose of this use case is to describe a series of events related to the creation of an allergic and intolerance list of conditions. This use case will also include the maintenance of the allergy and intolerance list. There is a former Primary Care Provider (PCP #1) and a new Primary Care Provider (PCP #2). Provider #3 prescribes a new medication that results in a new adverse reaction.

Conditions
Individual enrolls in practice of a primary care physician (PCP #2) as a new patient and remains an active patient. Patient is self referred to other providers and is seen in an emergency department.

Exclusions
Evaluation of the condition by an allergy specialist or confirmation of reactions by testing or direct challenge.

Preconditions
Individual has had previous primary care physician (PCP #1) who has created a list of allergies and intolerances that is part of the individual’s original paper medical record.

Use Case Sequence of Steps
1. A list of allergies and intolerances is created on intake by the patient’s new PCP (PCP #2)
2. The previous medical record is reviewed and reconciled with the patient history. PCP #2 creates the initial allergy and intolerance list of conditions.
3. The patient is subsequently seen by PCP #2 with a reaction to newly prescribed medication (trimethoprim/sulfamethoxazole) prescribed by Provider #3. The allergy and intolerance list is updated by PCP #2.
4. The patient is given an antibiotic by another provider (Provider #4) and has reaction that results in emergency room visit.
5. In the Emergency Room the physician attributes the adverse reaction to the antibiotic erythromycin, and adds erythromycin to the allergy and intolerance list.
6. A summary of the emergency visit is sent to PCP #2 by the emergency room with erythromycin allergy added to list.
7. PCP #2 reviews the emergency room summary and discusses the reaction history with the patient. PCP #2 then reconciles list of allergies and intolerances and updates the list.
Post Condition
Reconciled list of allergy and intolerances is part of patient record(s).

Actors
Patient – Eve Everywoman
PCP #1 – Former primary care provider
PCP #2 – Current primary care provider Patricia Primary
Provider #3 – Gynecologist Flora Fem
Provider #4 – Dermatologist Sophie Scratch
Emergency Room Physician – Eric Emergency

Use Case Scenario

Eve Everywoman is a 48 year old female who is visiting with her new primary care physician Patricia Primary (PCP #2) for the first time. She has brought a paper record from her previous primary care provider (PCP #1) which includes an allergy list. The allergy list details a severe allergy to penicillin and to kiwi fruit.

Eve Everywoman notes that at the age of four, she was given penicillin for strep throat and subsequently developed severe hives. According to her mother, the pediatrician advised that subsequent exposure to penicillin could be life-threatening. Those records are no longer available and her mother is deceased. Ten years ago at a restaurant, Eve ate kiwi from a salad bar and while still at the table experienced an itchy throat, swollen lips, and hives around the mouth. A companion gave her diphenhydramine to take and her symptoms resolved over the next few hours.

A review of systems by Patricia Primary (PCP #2) reveals a patient reported sensitivity to some types of sunscreens resulting in an itchy red weeping rash. This reported condition resolves without treatment. The reported sensitivity does not occur when Eve uses her favorite brand, including when she used it four days ago. Therefore at the time of the initial visit to PCP #2 the allergy and intolerance list contains a reported allergy to penicillin and kiwi, and sensitivity to certain types of sunscreen.

Six months later, Gynecologist Flora Fem (Provider #3) gives Eve trimethoprim / sulfamethoxazole for dysuria. After four days, Eve calls her gynecologist to report vaginal itching and is prescribed lotrimin. On day seven, Eve develops an itchy rash of purplish hives, sore red tongue, and red eyes (while still taking the antibiotic). Eve calls her primary care provider (PCP #2) who advises her to come in for an office visit. The primary care provider (PCP #2) diagnoses an allergy to sulfa drugs and tells her to stop the trimethoprim/sulfamethoxazole. She is advised to take diphenhydramine as needed every six hours and all of her symptoms resolve over the following week. PCP #2 adds a sulfa allergy to the allergy and intolerance list.

Three months after the diagnosis of the sulfa allergy, Eve visits Dermatologist Sophie Scratch (Provider #4) for adult acne. Erythromycin 250 mg bid is prescribed for one month. During the second week, Eve forgets to take the erythromycin until late afternoon so she
takes two pills at once. Thirty minutes later Eve has severe abdominal pain, nausea, vomiting and goes to the emergency department. In the emergency department, an x-ray and blood tests are performed. Phenegran is prescribed and the Emergency Room physician Eric Emergency diagnoses an allergy to erythromycin. Eve’s symptoms resolved by the time she left the emergency department. The emergency room summary has downloaded the allergy list from the local Health Information Exchange as a CCD and Eric Emergency has added an allergy to erythromycin.

The primary care provider (PCP #2) reviews Eve’s account of the episode and reviews the summary from the emergency department. PCP #2 advises Eve that the reaction to erythromycin is not an allergy, rather an episode of intolerance related to the dose. PCP #2 updates the allergy and intolerance list; the erythromycin allergy is changed to “inactive” and erythromycin intolerance is added to the list. This updated allergy and intolerance list is then available to other providers, and to the patient’s personal health record.

**Use Case 5: Assessment of Criticality**

*Discussion Paper: Severity and Criticality in the Model of Allergy and Intolerance Reactions – See Appendix A*

**Use Case Description**
The purpose of this use case is to demonstrate the assignment of a criticality attribute to a condition on an allergy and intolerance list with in an electronic health record and enabling the exchange of this attribute to other systems such as a PHR.

**Primary Actor**
*Attending physician* (pediatrician) – Karen Kidder
(Role: accessing EMR data; assessing adverse reaction and determining criticality of reaction/condition; documenting medical history, clinical findings and allergy/intolerance and adverse reaction with assessed criticality; authoring allergy and adverse reaction criticality information for updating PHR contents where applicable.)

**Other Actors**
*Patient(child)* – Kari Kidd
*Parents* (subject of care and parents as informant) Nelda and Ned Nuclear
*Pediatrician Clinic EMR/CIS* (documentation and authoring applications)
*PHR* (clinical and patient entered information repository; query/retrieval and documentation applications) [in Australia, this will be PCEHR]

**Assumptions**
- Pediatrician Practice has EMR/CIS that:
  - Provide access to Allergy/Intolerance and adverse reaction data
  - Support documentation of allergy/intolerance and adverse reaction details including criticality assessment
  - Support generation of allergy/intolerance and adverse reaction details with criticality assignment for transmission and
  - Updating PHR with recent adverse reaction details
Pre-conditions
The patient (child) presented to the pediatrician with signs and symptoms of an adverse reaction to a food substance.
The pediatric clinic uses an electronic medical record system supporting the documentation of the adverse reaction event, management and revision of allergy/intolerance list. Receiving systems (e.g. PHR) are capable of receiving allergy/intolerance and adverse reaction information.

Triggers
A child experiences an adverse reaction to a food substance (peanuts in this case) and presents at pediatric clinic for treatment. The pediatrician associates the adverse reaction to the ingested food and based on the clinical assessment assigns a criticality attribute to the condition.

Exclusions
Patient conditions which are not relevant to allergy/intolerance or adverse reaction topics

Use Case Sequence of Steps
1. The patient (child) presents at a pediatric clinic with an adverse reaction to food substance (peanut in this use case).
2. The patient’s parents provide information on medical history including history of known allergies and intolerances, medications and the details of the current adverse reaction to a food substance (peanut) immediately prior to presentation at pediatric clinic.
3. The pediatrician accesses the clinic EMR for the patient history/clinical information including allergy/intolerance and adverse reaction data.
4. The pediatrician does not find any pre-existing allergy/intolerance information on this patient.
5. The pediatrician evaluates clinical data from EMR and takes a full medical history from patient’s parent including any allergy/intolerance, and medication history.
6. The pediatrician also takes a full family history (e.g. parents) of allergies and intolerances.
7. The pediatrician evaluates the patient condition, makes a diagnosis, and determines the criticality of the adverse reaction to peanuts. The child is treated and provided a prescription of epinephrine auto-injector.
8. The pediatrician documents in EMRS the patient’s clinical details including medical history, presenting problem – signs and symptoms of allergic reaction to peanuts, medication history, new diagnosis (peanut allergy), assessing the peanut allergy adverse reaction criticality, treatment and outcomes.
9. The pediatrician creates/updates allergy/intolerance lists with an entry of peanut allergy, including the adverse reaction criticality assignment, and medical alert on allergy conditions.
10. The Pediatrician authors allergy details including the new diagnosis of peanut allergy, adverse reaction criticality for updating patient’s PHR.
Post-conditions
The clinic electronic medical record is updated with the identified allergy/intolerance condition – allergy to peanut, adverse reactions, reaction criticality and medical alerts. Allergy/intolerance and adverse reaction and assessed criticality information is also transmitted patient’s PHR where applicable (e.g. if requested by patient’s parents).

Notes
Allergy/intolerance details captured and exchanged include:
- medication class, medication name, dose, date/time of medication start, date/time of adverse reaction onset, adverse reaction details including assessed reaction criticality,
- date/time of presentation to hospital/primary care clinic, date/time of treatment and details,
- date/time of resolution, updated allergy/Intolerance list including assessed criticality details, informant/information provider (patient’s parents), author (may also be the attending physician).

Use Case Scenario

Event leading to presentation
A 4-year old girl, Kari Kidder, eats a single peanut at a family gathering. Within one minute she complains that her mouth feels funny. Within five minutes she has hives around his mouth, over her face and neck and on her trunk that she complains are very itchy. She appears nauseated and has a single episode of vomiting. Kari is taken by her parents to her pediatrician’s clinic where she is seen by her pediatrician.

Presentation
By the time of arrival 20 minutes later Kari’s hives have disappeared and she says she feels okay.

Medical & Family History
The pediatrician obtains the history of the episode from Kari’s parents who assert that Karen has never had any previous such episode. Both parents have seasonal nasal allergies and the mother has a history of allergy to penicillin as a child.

Physical Exam
No abnormality detected on examination by the pediatrician

Diagnosis
The pediatrician establishes the diagnosis of the episode as a mild allergic reaction to peanuts. Based on the clinical history, the pediatrician assesses the condition to have an attribute of high criticality.

Management
The pediatrician advises the parents that the child should avoid peanuts and all foodstuffs containing any form of peanuts. The pediatrician provides a prescription for an epinephrine auto-injector and provides instructions on how to use the epinephrine auto-injection for any
future episodes that appear to be more severe or are worsening; and that if this is used they should call for an ambulance or proceed to an emergency department.

Outcomes
The adverse reaction resolved without the need for intervention and with no residual functional impairment or consequences. The patient’s medical record at the clinic is updated with the diagnosis of mild allergic reaction to peanut with assigned attribute of high criticality. Allergy to peanuts is included on the list of allergies and intolerance in the patient’s medical record with an attribute of high criticality.

Allergy and adverse reaction to peanut criticality details are transmitted to patient’s PHR as requested by patient’s parents.

Criticality Attribute – Examples/Condition of Use

Criticality is an attribute of a condition on the list of allergies and intolerances. The conditions on that list are an assertion of a predisposition of the individual to have a specified type of adverse reaction if exposed to a specified substance in the future. The criticality attribute represents a clinical judgment as to the worst case for the severity of a future reaction.

The severity of a previous reaction informs the clinical judgment about criticality of the condition. It is not however a direct relationship. Many allergy and intolerance reactions have a dose response curve and this is in part related to the route of exposure. An oral dose of a medication might produce only a mild reaction because subsequent vomiting eliminates most of the dose before it is absorbed, while an intravenous dose of the same medication might produce a severe, life threatening reaction. For Type I allergic reactions, those which cause anaphylaxis, there is a “booster effect” as there is with an immunologic (protective) reaction to an immunization. A first reaction which is mild, may lead to enhanced allergic antibody production and a subsequent exposure at a later date may result in a severe reaction.

1. If a condition exists and based on the clinical assessment of the known condition and episode of adverse reaction that there is possibility of a future adverse reaction of likely life threatening outcome, a value of “critical” may be assigned to the criticality attribute.
2. If a condition identified in the medical history or in the allergy/intolerance list does not have the “critical” value assigned to the criticality attribute, a clinician would review documented clinical data and interview/assess the patient to reach a conclusion.
3. If a condition is clinically assessed to be non-critical, a value of “non-critical” may be assigned to the criticality attribute
4. If allergy/intolerance information received from external sources does not contain criticality assessment value or it may be impossible to determine criticality value (e.g. parents or guardian of small child unable to provide adequate and relevant information about the condition), a null favor value (e.g. unknown, unable to determine) may be assigned.
Use Case 6: Immunization with Known Allergy

Use Case Description
The purpose of this use case is to illustrate the case where a young patient has to receive a vaccine for yellow fever before going to Africa with his parents. The young patient is known to have allergic sensitivity to eggs. After successful immunization, a report is sent to his pediatrician with a suggestion that a referral is be made to an allergist for further testing.

Conditions
A child allergic to eggs must undergo yellow fever immunization under medical supervision.

Exclusions
Patient condition(s) which are not relevant to allergy/intolerance or adverse reaction topics.

Preconditions
The patient is brought to a travel clinic for the appropriate yellow fever immunization before traveling to Africa with her parents. The mother has with her the medical record summary of her child indicating an allergy to eggs. There is no prior reaction to usual childhood vaccines.

Use Case Sequence of Steps
1. Mother arrives at travel clinic with her child who is 8 years old
2. Nurse reviews medical history of child where the allergy and intolerance list indicates an allergy to eggs. The nurse refers the patient to an attending immunization specialist physician.
3. Note – package insert indicates this vaccine is contraindicated for those with a known egg allergy.
4. Physician conducts case history and decides to administer vaccine under his personal supervision.
5. Physician assisted by nurse administers the yellow fever vaccine, constantly monitoring patient reactions, ready to intervene with proper medication if necessary.
6. Nurse monitors patient for a period of time until assured of lack of adverse reactions for one hour.
7. Physician writes a consult note for the patient pediatrician, adds a note to the patient summary record, and signs the International Certificate of Vaccination. The physician notes that the vaccine was administered without adverse reaction.
8. Physician documents in the medical record the administration of the vaccine, the known contraindication and the decision/rationale to provide the vaccination.

Post Conditions
Patient has received the vaccine and has been released without adverse reaction. The patient summary record is update to reflect the provision of the vaccine despite the known allergy.
International Certificate of Vaccination filled and signed.
Use Case Scenario
An 8 year old child with mother requests a yellow fever vaccine as they will be traveling in the next several months.

Medical History:
Previous adverse reaction to eggs that required emergency medical intervention and hospitalization
Route of exposure: food ingestion
Severity of symptoms: see note below
Type of reaction: hyper-sensitivity symptoms (urticaria, swelling of the mouth and throat, difficulty breathing)
Age: child was 2 year old
Time after exposure before onset of symptoms: symptoms began during meal after a few bites of scrambled eggs
Resolution: all symptoms resolved during a 24 hour hospitalization with no apparent residual
Other allergic or intolerance history: none

Note: egg allergy is defined as an IgE-mediated hyper-sensitivity causing symptoms like, but not limited to, urticaria, swelling of the mouth and throat, difficulty breathing or hypotension. (CIG, p. 85)

Vaccine
YF-VAX®

Note: The yellow fever vaccines (a live vaccine) are prepared from virus grown in chick embryos and are the most likely to cause allergic reaction in egg- or chicken-allergic individuals. (CIG, p. 85)
Note: YF-VAX®, a live virus vaccine, is prepared in chick embryos from the attenuated 17D strain, is lyophilized and contains sorbitol and gelatin as stabilizers. There is no preservative in the vaccine or the accompanying diluent. (CIG, p. 345)

Examinations:
Individual risk assessment of child by physician

Blood Tests:
Not applicable

Diagnosis:
Possibility that child has less sensitivity to eggs. The physician determines that the vaccination for yellow fever is more important. Therefore vaccination should be conducted but under close medical supervision.

Note: Egg allergy is one of the most common food allergies of childhood, with a prevalence of 1%-3% in children under 3 years of age. As most children outgrow their egg allergy, the prevalence in adulthood is much lower. (CIG, page 85)

Vaccine administration
Subcutaneous

Post vaccine supervision
Medication on hand: aqueous epinephrine 1:1000; diphenhydramine hydrochloride (Benadryl®), resuscitative equipment appropriate for children.

Note: As avoidance is not always possible, every vaccine provider should be familiar with the symptoms of anaphylaxis and be ready to initiate management and administer appropriate medications. Most instances begin within 30 minutes after an injection of vaccine; shorter intervals to onset foretell more severe reactions. Thus vaccine recipients should be kept under supervision for at least 15 minutes after immunization; 30 minutes is a safer interval when there is a specific concern about possible vaccine allergy. (CIG, p. 80)

Note: The cardinal features of anaphylaxis are itchy, urticarial rash (in over 90% of cases); progressive, painless swelling (angioedema) about the face and mouth, which may be preceded by itchiness, tearing, nasal congestion or facial flushing; respiratory symptoms, including sneezing, coughing, wheezing, labored breathing and upper airway swelling (indicated by hoarseness and/or difficulty swallowing) possibly causing airway obstruction; hypotension, which generally develops later in the reaction and can progress to cause shock and collapse. Gastrointestinal symptoms like nausea, vomiting and diarrhea may occur with anaphylaxis (CIG, p. 81)

Outcomes
Patient has received the vaccine and has been released without significant adverse reaction. The patient summary record is updated indicating the evaluation of the allergic conditions and decision to administer the yellow fever vaccine under medical supervision. The International Certificate of Vaccination filled and signed and a consult note is sent to pediatrician.

References
- Reactions to 17D yellow fever vaccine are typically mild.... Immediate hypersensitivity reactions, characterized by rash, urticaria, or asthma, are uncommon (i.e., an estimated incidence of 1/130,000--250,000) and occur principally among persons with histories of allergies to egg or other substances (26). Gelatin is used as a stabilizer in different vaccines, including yellow fever vaccine. Gelatin has been implicated as a cause of allergic reaction related to other vaccines and, therefore, might also do the same regarding yellow fever vaccine (27--29). (Yellow Fever Vaccine Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2002- [http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5117a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5117a1.htm))
- The American College of Allergy, Asthma and Immunology and the American Academy of Allergy, Asthma and Immunology issued joint practice parameters in
2011 for influenza immunization in individuals with a history of anaphylaxis after egg ingestion. Recommendation is for egg allergy less severe than anaphylaxis, give immunization in pediatricians office. For those with anaphylactic history, administer in allergist office. They cite a study of 185 individuals with “convincing” history of anaphylaxis after egg in which there were no reactions to routine influenza immunization. Influenza immunization is admittedly not yellow fever immunization, but I think this is a reflection of diminishing level of risk as manufacturing techniques for vaccines have improved over the years. (Dr. Russell Leftwich)(reference) http://www.aaaai.org/Aaaai/media/MediaLibrary/PDF%20Documents/Practice%20and%20Parameters/Egg-Allergy-and-Influenza-Vaccine-112111.pdf

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• Dr. Russell Leftwich, Chief Medical Informatics Officer, Office of eHealth Initiatives, State of Tennessee; FAAAAI - Fellow of the American Academy of Allergy, Asthma, & Immunology

Use Case 7: Allergic Reaction to a Device

Use Case Description

The purpose of this use case is to describe an adverse reaction to latex in a jejunostomy feeding tube implanted into a teenage patient with a severe disability. The adverse reaction was reported by the patient’s family to the US Food and Drug Administration as an adverse event.

Conditions

This use case is an example of an adverse reaction that can occur due to latex in an implanted device. Even though the patient was wearing a wrist band identifying her adverse reaction to latex and the device label stated that the device contained latex, the device was implanted in the patient.

Exclusions

There are no exclusions associated with this use case.

Preconditions

• The patient had surgery to implant a polyurethane central line and jejunal feeding tube.
• The patient has a known adverse reaction to the use of latex gloves touching her skin which is documented on the allergy and intolerance list.
Use Case Sequence of Steps
1. The patient requires the implantation of a jejunal feeding tube, requiring a surgical procedure.
2. Patient’s family notified the hospital of the patient’s reaction to the use of latex gloves.
3. A pre-surgery workup of patient of the patient was conducted.
4. Surgery was performed implanting a polyurethane central line and a latex jejunal feeding tube.
5. The patient developed a rash as well as red spots on chest and shoulders post-surgery.
6. A post-surgical visit reveals that a tube with latex was inserted in patient.
7. The surgeon removed tube two weeks post original surgery substituting a non-latex alternative jejunostomy feeding tube.
8. Patient’s allergy and intolerance list, which already includes an allergy to latex, is updated with the details of the adverse reaction to the latex feeding tube.

Post Condition
Device is not returned to manufacturer.

Use Case Scenario
The patient is a teenager with a severe disability rendering her unable to take anything by mouth. The decision is made to place a central line and a jejunal feeding tube to ensure the patient receives adequate nutrition.

Medical History:
As part of the pre-operative surgical appointment, the patient presents as a slightly underweight young female who is unable to answer questions on her own. Her mother notes that the patient is now aspirating on foods and liquids offered by mouth. No allergies or intolerances are noted at this visit, except that the mother has noted that she and other health care providers have not been able to wear latex gloves when they provide care to the patient as latex seems to irritate the patient’s skin.

Surgery:
A jejunal feeding tube and polyurethane central line were implanted in patient. The patient recovered from the procedure with incident and was released home on a standard liquid tube feeding.

Post Operative Findings
A one week post-operative visit indicated no issues with the feeding tube or central line sites. Approximately two weeks after the surgical insertion of the feeding tube, the mother noted a rash around the tube insertion site which expanded to the abdomen. There were also red spots on the chest and shoulders. The patient returned to see the surgeon for a second post-operative visit. The surgeon reviewed the patient’s chart as well as the operative note and realized that the jejunal tube used contained latex based on the review of the product label. The surgeon then removed the latex feeding tube and replaced it with a non-latex based tube.
**Diagnosis:**
The surgeon determined that the patient had an allergic reaction to the latex in the implanted jejunal feeding tube.

**Treatment:**
The latex jejunal feeding tube was removed and a non-latex tube was inserted.

**Outcome:**
The patient recovered from the second procedure without incident. The surgeon updated the patient’s allergy list to include a known observed allergy to latex.

*Note: Information was added to this use case for the purpose of this exercise.*

Special thanks to Erin Fields, US FDA for the development of this use case.

**Use Case 8: Misattribution of an Allergy**

**Use Case Description**
The purpose of this use case is to describe a misattribution of an adverse reaction to a knee implant presumed to be an allergy to nickel. The adverse reaction was reported by the health professional to the device manufacturer who then sent the report to the US Food and Drug Administration (FDA).

**Conditions**
This use case is an example of an adverse reaction that can occur due to an implanted medical device. Patients may have adverse reaction to the medical device or to other factors related to the implant procedure or the ongoing use of the medical device.

**Exclusions**
The patient was presumed to not be on any immunosuppressant medications at the time of the event.

**Preconditions**
The patient had no known allergies or intolerances at the time of the surgery.

**Use Case Sequence of Steps**
1. Prior to surgery, the surgeon worked up patient for partial knee arthroplasty.
2. There were no known allergies or intolerances at time of workup including no known allergies to metals or jewelry.
3. Patient had a partial knee arthroplasty.
4. The patient returned to the surgeon for a post-operative appointment seven months after surgery complaining of joint pain and a swollen knee.
5. The surgeon observed that the knee was filled with blood.
6. Surgeon drained the knee and ordered test and x-rays. The tests were negative for infection and the x-rays did not show implant misalignment.
7. Based on the apparent intolerance to the original implant, the surgeon converted the partial knee to a total knee procedure.
8. The surgeon noted no loosening of the implant components during the second procedure. The patient’s synovium, however, was bloodstained.
9. The surgeon concluded that this adverse reaction was an allergy to the nickel in the implant and add a new condition to the allergy and intolerance list; allergic to nickel. The surgeon also reported the event to manufacturer.
10. Subsequently, the patient underwent an evaluation by an allergist to verify the allergy to nickel.
11. No allergy to nickel was found, and the allergist updated the allergy and intolerance list. The allergy to nickel was made inactive, but remained on the allergy list for future reference. The adverse reaction to the implant was attributed to a dermatitis reaction related to the presence of the metal.

Post Condition
1. The manufacturer of RESTORIS Multicompartamental Knee System conducted an evaluation of the event as part of their complaint follow-up process.

Actors
Patient – Adam Everyman
Orthopedic Surgeon – Calvin Carpenter
Allergist – Ramsey Reaction

Use Case Scenario

Medical History
The patient Adam Everyman is a 58 year old male with a chief complaint of arthritis in his knee. The patient visits Calvin Carpenter, an orthopedic surgeon who recommends a partial knee arthroplasty to restore full joint functionality. The patient’s electronic health record allergy and intolerance list indicates that the patient has “no known allergies or intolerances” and the patient confirms that he has no allergies to intolerances including any types of metal or jewelry. The only other surgery the patient has had is successful hernia repair at the age of 49.

Initial Surgery:
The patient underwent partial knee arthroplasty using the RESTORIS Multicompartamental Knee System which includes nickel. The initial post-operative period was uneventful and the patient successfully completed rehabilitation therapy.

Manifestation of Reaction:
The patient returned to the surgeon for a post-operative appointment seven months after surgery complaining of joint pain and a swollen knee. The surgeon observed that the knee was filled with blood. Calvin Carpenter, the surgeon drained the knee and ordered tests and x-rays. The tests were negative for infection and the x-rays did not show implant misalignment.

Second Surgery:
Based on the apparent intolerance of the original implant, the surgeon converted the partial knee to a total knee procedure using a Smith & Nephew OXONIUM Total Knee System. The surgeon noted no loosening of the implant components during the second procedure. The patient’s synovium, however, was bloodstained.

Outcome:
The surgeon concluded that the adverse reaction to the initial implant was an allergic reaction to the nickel. The surgeon then added a new condition to the allergy and intolerance list; allergic to nickel. The surgeon also reported event to manufacturer.

Allergy Testing:
Subsequently, the patient underwent an evaluation by an allergist to verify the allergy to nickel. Based on a skin prick test, no allergy to nickel manifested, and the allergist updated the allergy and intolerance list. The allergy to nickel was changed from active to inactive.

*Note: Information was added to this use case for the purpose of this exercise.

Special thanks to Erin Fields, US FDA for the development of this use case.

Use Case 9: Known Allergy is Resolved

Use Case Description
The purpose of this use case is to describe a situation where there is a known allergy that is resolved. The resolution of the allergic condition triggers an update to the condition on the patient’s allergy list.

Conditions
This use case presumes a known allergy that is documented on the allergy list. The allergy resolves over time. In this case the resolution is due to the attenuation of the immune system of the patient.

Exclusions
This use case does not consider the use of allergy desensitization therapies.

 Preconditions
The patient is known to be allergic to cow’s milk. At seven months of age, the patient Kari Kidder was started on cow’s milk based formula. Within 10 minutes of taking her first bottle of cow’s milk formula, Kari developed a rash and vomited the formula. An immediate visit to the pediatrician Karen Kidder resulted in the pediatrician determining based on the mother’s observation that there was a relationship between the cow’s milk formula and manifestation of an adverse reaction to the formula by Kari Kidd. Kari was switched to a protein hydrolysate based infant formula and Kari’s mother was told to avoid feeding Kari any milk or milk products. The pediatrician documented a milk allergy in the electronic health record allergy list. The milk allergy was confirmed by a skin prick test. The avoidance of milk and milk products was successful in preventing further adverse reactions to milk.
Use Case Sequence of Steps

1. Kari Kidd is now a four year old. Kari has avoided milk and milk-based products since the age of 7 months.
2. Kari visits the pediatrician Karen Kidder for her annual physical exam. The pediatrician notes the milk allergy and asks Kari’s mother Nelda Nuclear if any milk or milk products have been included in Kari’s diet.
3. Nelda notes that no fluid milk has been provided but that occasionally Kari has eaten small amounts of baked goods containing milk without any reaction since the age of three. No fluid cow’s milk or milk products have been provided.
4. The pediatrician recommends a food challenge to determine if Kari has developed a tolerance to milk and milk products.
5. A food challenge without any reaction demonstrates that Kari is no longer manifesting a reaction to milk.
6. The pediatrician determines that based on the results of the food challenge that Kari is no longer allergic to milk and updates the milk allergy on the allergy list to “resolved”.

Post Condition

- Kari is now able to consume milk and milk products without reaction.

Actors

Pediatric Patient – Kari Kidd
Mother – Nelda Nuclear
Pediatrician – Karen Kidder

Use Case Scenario

Kari Kidd is a four year old with a known allergy to milk. At the age of seven months, Kari’s mom Nelda Nuclear switched Kari from breast milk to a cow’s milk based formula. Based on the infant’s immediate reaction to cow’s milk based formula, the pediatrician diagnosed an allergy to milk. A subsequent skin prick test confirmed the diagnosis of a milk allergy. Kari was switched to a protein hydrolysate-based formula and as solids are introduced into the diet, Kari avoids all milk and milk products. The pediatrician documents an allergy to milk on the electronic health record allergy list.

By the age of three, Kari is able to tolerate baked goods that contain milk without an adverse reaction. During a visit to the pediatrician Kari’s mom notes that baked goods with milk as an ingredient can now be tolerated. The pediatrician recommends a food challenge to determine if Kari has “outgrown” her milk allergy. Following ingestion of increasing amounts of milk without reaction, the pediatrician determines that Kari is indeed able to tolerate milk and milk products without an adverse reaction.

The pediatrician updates Kari’s electronic health record allergy list to show that the milk allergy is now “resolved”. Kari is now able to consume milk and milk products without reaction.
References


Use Case 10: Unable to Determine Triggering Agent

Use Case Description

The purpose of this use case is to support the documentation of the assertion of “unable to determine a specific trigger of allergy/intolerance reactions” (to multi-ingredient medications) for a patient who experienced adverse reactions several hours after administration of multi-ingredient medication. The information is then captured in hospital clinical information systems/EMRS; and to support the generation and exchange of such information in a hospital discharge summary, generation of allergy/intolerance and adverse reaction information for transmission to patient’s nominated community pharmacist, and for updating patient’s PHR where appropriate.

Primary Actor

Attending physician - Horace Hippocrates
((Roles: accessing EMR data; documenting medical history, clinical findings and allergy/intolerance and adverse reaction information; authoring of discharge summary; updating PHR contents where applicable)

Other Actors

Patient (subject of care and informant; updating PHR where appropriate) – Eve Everywoman
Attending physician (accessing EMR data; documenting medical history, clinical findings and allergy/intolerance and adverse reaction information; authoring of discharge summary;
Assumptions

Hospital has EMR/CIS that:

- Provide access to Allergy/Intolerance and adverse reaction data
- Supports documentation of allergy/intolerance and adverse reaction details
- Supports generation and exchange of discharge summary/event summary containing allergy/intolerance and adverse reaction details; and adverse reactions details to be sent to nominated community pharmacist
- Updates PHR with recent adverse reaction details

Pre-conditions

- Causality relationship between the exact medication ingredient (of the multi-ingredient medication that triggered the reaction) and the ensuing adverse reaction could not be identified

Triggers

A patient experienced signs and symptoms of adverse reactions several hours after administration of a multi-ingredient antibiotic prescribed to treat her urinary tract infection which developed soon after her hip replacement operation in hospital. The adverse reaction was investigated. Adverse reactions to the multi-ingredient medication identified. The specific ingredient as trigger to the reaction was unable to be identified.

Exclusions

Patient’s adverse reactions can be positively associated as allergy or intolerance reaction to a specific agent or ingredient (e.g. one of the ingredients of a multi-ingredient medication) during or subsequent to onset of the reactions.

Use Case Sequence

1. Patient was administered a dose of multi-ingredient antibiotic to treat urinary infection
2. Patient exhibited signs and symptoms of adverse reactions shortly after administration of the medication
3. Attending physician assessed patient’s full history of allergy/intolerance and physical examination;
4. Multi-ingredient medication was identified to be the trigger but the exact ingredient that might be the cause of the adverse reaction could not be identified
5. Attending physician accessed hospital EMR access to retrieve patient medication history and allergy/intolerance details.
6. No previously known allergy/intolerance or adverse reaction to the multi-ingredient medication in question was identified
7. Attending physician made a diagnosis of patient’s condition as adverse reactions to the multi-ingredient medication in question
8. Attending physician prescribed appropriate intervention(s) including treating signs and symptoms of adverse reactions, cancellation of the prescription for the multi-ingredient medication in question
9. Attending physician documented presenting problems, new diagnosis of allergy/intolerance to the multi-ingredient antibiotic (co-trimoxazole), updating allergy/intolerance details, intervention(s) and outcomes
10. Attending physician creates/updates allergy/intolerance lists in clinical information system or EHRS with new entry of allergy/intolerance to multi-ingredient antibiotic with no attribution to a specific ingredient
11. Patient recovered from adverse reactions without further consequence
12. Attending physician authored discharge summary generated using hospital clinical information system or EMRS on patient’s discharge. The discharge summary contains allergy/intolerance list with newly identified multi-ingredient antibiotic as an item with no attribution to a specific ingredient as the causative agent
13. Attending physician authored in EMRS allergy/intolerance and adverse reactions details for transmission to patient’s community pharmacist where applicable
14. Attending physician updated PHR with relevant clinical details where appropriate (as consented by patient)

**Post-conditions**

(1) Updated EMRS record with diagnosis, new entry of multi-ingredient antibiotic to allergy/intolerance list, adverse reaction details, and “Unable to determine allergy/intolerance agent or trigger” information
(2) Hospital discharge summary includes allergy/intolerance details to multi-ingredient antibiotic and entry on “Unable to determine allergy/intolerance agent or trigger” to the multi-ingredient medication given
(3) Allergy/intolerance and adverse reaction information also transmitted patient specified pharmacy(ies) and PHR where applicable
(4) PHR updated with relevant clinical information including allergy/intolerance and adverse reaction information

**Notes**

*Allergy/intolerance details captured and transmitted include:*
medication class, medication names, dose, datetime of medication start, datetime of adverse reaction onset, adverse reaction details, datetime of presentation to hospital/ED, datetime of treatment and details, datetime of resolution, updated allergy/intolerance list, informant/information provider (patient), author (treating physician)
**Use Case Scenarios**

A 66-year old female exhibited signs and symptoms of urinary tract infection on Day 3 post-op after right total hip replacement. Patient was prescribed sulfamethoxazole/trimethoprim (co-trimoxazole) 800/160 mg orally every 12 hours. Approximately 3 hours after the administration of the first dose of the medication, the patient started to exhibit signs and symptoms of adverse reactions including: gastrointestinal disturbances (anorexia, nausea, vomiting) and allergic skin reactions (such as rash /urticaria and itching), and wheezing.

Her *presenting complaints* include:

Gastrointestinal disturbances (anorexia, nausea, vomiting) and allergic skin reactions (such as rash /urticaria and itching), and wheezing. Time lapse between medication administration and onset of symptoms appropriately 3 hours

No other sign/symptom elicited

**Medical History:**

Hypertension

Ischaemic heart diseases (Class II Angina)

Severe arthritis of right hip with functional disability admitted for total hip replacement

**Medications:**

Metoprolol: 50mg twice per day

Isosorbide dinitrate (extended release): 40mg once daily

Diclofenac: 50mg three times daily

Glucosamine sulphate: 1500mg per day

Chondroitin sulphate: 800mg per day

Fish oil 4000mg two times per day

**Allergy/Intolerance History**

Morphine pseudoallergy (symptoms include: flushing, hives, itchness, sweating and mild hypotension.

**Physical Examinations:**

Mild anorexia, nausea vomiting

Abdomen: soft, hyperactive bowel sounds, abdominal cramps

Respiratory: mild wheezing, no cyanosis

Urticarial skin rash, itchiness; redness to face

**Diagnosis:**

Given the timing of medication administration and appearance of adverse reactions, it is probable that this is a case of adverse (allergic) reaction to multi-ingredient medication sulfamethoxazole/trimethoprim

Differentiating which ingredient is the most likely trigger to the adverse reaction is difficult / impossible

**Treatment:**

Stop further administration of sulfamethoxazole/trimethoprim

Supportive treatment for adverse reaction signs and symptoms
Outcomes:
- Adverse reaction signs and symptoms resolve gradually after withdrawal of offending medication
- A diagnosis of adverse (allergic) reactions to sulfamethoxazole/trimethoprim was established. But specific trigger of the adverse reaction was not identified
- The allergy/intolerance list was updated with entry of adverse (allergic reactions) to sulfamethoxazole/trimethoprim and recording statement of “Unable to determine specific trigger to adverse (allergic) reactions”
- Hospital EMRS on this patient is updated with adverse reaction details and statement on “Unable to determine specific trigger to adverse (allergic) reactions”
- On discharge of patient:
  - Discharge summary sent to primary care physician/GP including updated allergy/intolerance list with information on adverse (allergic) reaction to sulfamethoxazole/trimethoprim and statement on “Unable to determine specific trigger to adverse (allergic) reactions”
  - Allergy/intolerance details were also transmitted patient specified pharmacy(ies) and PHR

Use Case 11: No Known History of Allergies or Intolerances

Use Case Description
The purpose of this use case is to support the documentation of the assertion by patient or his/her guardian that there, to the best of his/her knowledge there is no known history of allergy or intolerance and adverse reaction to medications or substance. The information is then captured in hospital clinical information systems/EHRS; and to support the generation and exchange of such information in a hospital discharge summary.

Conditions
A patient involved in a minor motor vehicle accident (MVA) presented at the Emergency Department for treatment and is assessed for history of allergy/intolerance to any medications, foods and environmental agents as part of medical history assessment and examination procedures.

Exclusions
Patient with positive history of allergy/intolerance or adverse reaction to one or more medication(s) or substance(s).

Preconditions
- Patient presented to hospital with for care/treatment.
- The hospital uses electronic medical record systems supporting the documentation of the adverse reaction event, management and revision of allergy/intolerance list
- Hospital electronic clinical information system/EHRS capable of generating and transmitting electronic discharge summary

Use Case Sequence of Steps
1. The patient presents to the Emergency Department following a minor motor vehicle accident.
2. The patient was assessed with a full medical history and physical examination by the attending physician.
3. A complete review of any known allergy/intolerance to any medications, foods and environmental agents is assessed as part of the medical history.
4. The patient condition related to the accident was diagnosed and treatment was given.
5. Documentation of presenting problem, medical history, medication history, treatment and outcomes with creation/update of allergy/intolerance list in hospital clinical information system or EHRS was completed.
6. Discharge summary generated using hospital clinical information system or EHRS

Post Conditions
Updated EHRS record with “no known allergy/intolerance” entry to allergy/intolerance list
Hospital discharge summary includes “no known allergy/intolerance and adverse reaction” information
Patient also offered the option of updating his PHR with “no known allergy/intolerance and adverse reaction” information

Use Case Scenario
A 45-year retired male footballer had a minor collision with a taxi while riding his bicycle into an intersection of a road and suffered from minor concussion. He was taken to the ED of a local hospital by an ambulance.
This was the patient’s first encounter at the hospital ED.
His presenting complaints include:
Momentary loss of consciousness for approximately 1-2 minutes immediately after collision
Mild headache with no nausea, no vomiting
Bruises to left shoulder, left upper arm and antero-lateral aspect of left lower chest
Skin abrasions on antero-lateral aspect of left leg with moderate to severe pain

Medical History:
Bilateral secondary osteoarthritic knee (sports injuries related)
Otherwise relatively healthy male with regular exercise.
The patient was asked the following questions on any allergy/intolerance and adverse reaction details:
Had the patient ever experienced any [allergic/intolerance] bad reaction(s) to the following agents?
   • Any medications – prescribed, over-the-counter, naturopathy/herbal substances
   • Any foods or food ingredients
   • Any environmental agents such as animal hair/fur or dander
If the patient had never experienced any allergic/intolerance reactions to the above substances/agent, had the patient ever been told, e.g. by parents/guardians that he previously had suffered any such allergic/intolerance reactions or known to have the condition?
Patient answered “no” to the above questions and it was concluded that patient had denied any known history of allergy or intolerance to any medication or substance. The patient denied any relevant family medical history.
**Medications:**
Glucosamine sulphate: 1500mg per day
Chondroitin sulphate: 800mg per day
Fish oil 4000mg two times per day
Panadeine Forte (paracetamol 500mg + codeine phosphate 30mg) 2 tablets 6 hourly whenever necessary for knee pain relief

**Physical Examination:**
Blood pressure: 145/85 mmHg (likely to be stressed related)
Heart: rate = 92/min, no murmur, no added HS, ECG = sinus rhythm, no ischaemia
Neurological:
- Minimal concussive amnesia
- Moderate headache
- No convulsion
- No photophobia
- No muscle weakness
- No sensory loss
- No nausea, no vomiting
  - Pupils: R+L = approx. 4mm, equal and briskly reactive to light
Neck: no bruise, no haematoma, skin intact, no tenderness, no limitation to range of motion
Left shoulder, upper arm and chest revealed bruises
Shoulder joints, elbow joints, wrist joints, hip joints, knee joints, ankle joints: no swelling, no tenderness, no limitation to range of motion
Left leg: skin abrasion measuring 5cm X 12cm with uneven depth of dermal loss consistent of abrading injury
Respiratory, CNS, Abdomen/GI, Genito-urinary: NAD

**X-Rays:**
Skull – reviewed no bony injury
Chest – reviewed no bony injury
Left shoulder, upper and lower arms and hand – reviewed no bony injury
Left femur; tibia and fibula – reviewed no bony injury

**Diagnosis:**
Motor vehicle accident induced injuries including:
- Mild concessional injury
- Abrading injury to skin of left anterio-lateral aspect of left leg.

**Treatment:**
Hourly neurological observations for 4-6 hours
Paracetamol 1000mg 6 hourly
Surgical toilet and dressing to abrading skin injury
Discharge to care of General Practitioner after completion of neurological observations confirming no adverse neurological consequence

**Outcomes:**
- Surgical toilet and dressing given to skin wound.
- The allergy/intolerance list of conditions was updated with entry of “no known allergy/intolerance to medication or substance”.
• Patient discharged home with non-narcotic analgesic (e.g. paracetamol)
• Hospital EHRS on this patient is updated with “no known allergy/intolerance to medication or substance” information
• Discharge summary sent to primary care physician including “no known allergy/intolerance to medication or substance” information.
• Patient was offered the opportunity for his PHR to be updated with the latest medical history including the “no known allergy/intolerance and adverse reaction” details

**Use Case 12: Allergy and Intolerance Information Not Asked**

**Use Case Description**
The purpose of this use case is to support the documentation of unable to obtain information about patient history on allergy or intolerance and adverse reaction to medications or substances. The information is then captured in hospital clinical information systems/EHRS; and to support the generation and exchange of such information in a hospital discharge summary.

**Conditions**
A homeless, alcoholic patient fell from height; sustained serious head trauma, and is taken to an Emergency Department for neurological assessment and treatment. Patient is unable to provide any past and present medical history information including history on allergy/intolerance to medications or substances. No previous medical history on this patient from any other source is available to the clinicians at the hospital where this patient is treated.

**Exclusions**
Patient with positive history of allergy/intolerance or adverse reaction to one or more medication(s) or substance(s) or patient with ability to provide definitive allergy/intolerance information.

**Preconditions**
Patient is admitted to hospital with for care/treatment. The hospital uses electronic medical record systems supporting the documentation of the adverse reaction event, management and revision of allergy/intolerance list. Hospital electronic clinical information system/EHRS capable of generating and transmitting electronic discharge summary.

**Use Case Sequence of Steps**
1. The patient presents to the Emergency Department.
2. The patient was assessed by emergency room physician
3. The patient condition was diagnosed and treatment was given
4. The emergency room physician documents the presenting problem, medical history, medication history, treatment and outcomes with creation/update of allergy/intolerance lists in hospital clinical information system or EHRS
5. Patient was transferred to State hospice service for ongoing care
6. Discharge summary generated using hospital clinical information system or EHRS

Post Conditions
Updated EHRS record with “allergy/intolerance history not asked – cognitively impaired patient” (or “allergy/intolerance history cannot be obtained”) entry to allergy/intolerance list
Hospital discharge summary includes “allergy/intolerance history not asked” information

Use Case Scenario
A 54 year old homeless male fell from the stair of the upper level car park of local shopping centre while scavenging for drink cans and bottles in the car park rubbish bins. He sustained a serious head injury. He was discovered by a supermarket trolley attendant some unknown time after the injury and was taken to the emergency department of a local hospital by an ambulance. Patient was not known to the hospital. No previous medical history on this patient from any other source could be identified by the hospital.

The patient’s presenting problems include:
- Alerted level of consciousness (GCS = 8 [EO:2; MR:3; VR:3])\(^1\) on presentation
- Large left fronto-temporal haematoma (3 X 5 cm)
- Skin laceration (2 X 3.5 cm) over haematoma, bone structure not exposed
- Restless
- Incontinent
- Strong smell of alcohol in exhaled breath

Medical History:
Cannot be obtained

History of allergy or intolerance not asked – patient has alerted level of consciousness and cognitively impaired

Medications:
Medication history not asked - patient has alerted level of consciousness and cognitively impaired.

Physical Examinations:
Blood pressure: 168/90 mmHg; widened pulse pressure: 78 mmHg
Heart: rate = 62/min, rhythm: irregular

Neurological:
  Restlessness
  GCS = 8 (EO:2; MR:3; VR:3)
  No convulsion
  Pupils: dilated non-reactive left pupil
  Respiration: rate = 14-25; rhythm = irregular
  Monoparesis: left lower limb
  Abnormal/brisk reflexes
  Urinary incontinence

\(^1\) Many of patients who develop intracranial haematoma are comatose on admission. However, approximately 50% of patients with head injuries who require emergency neurosurgery present with head injuries that are classified as moderate or mild (Glasgow Coma Scale scores 9-13 and 14-15, respectively).
Other systems/organs:
Skull: large left fronto-temporal haematoma (3 X 5 cm); Skin laceration (2 X 3.5 cm) over haematoma
Neck: no sign of cervical spine injury
Chest: no sign of internal organ injury
Abdomen: no sign of internal organ injury;
Liver: firm, palpable mass 4 cm beyond right lower rib border
Liver function tests: abnormal liver enzyme results consistent with alcoholic cirrhosis
Upper and lower limbs: no abrasion or laceration

X-Rays:
MRI findings: linear fracture seen in left parietal bone; Left convexity acute subdural haematoma; Left fronto-temporal scalp acute haematoma
No other bony injury detected on X-rays

Diagnosis:
Alcoholic cirrhosis of liver
Left fronto-temporal scalp laceration and acute haematoma
Linear fracture of left parietal bone with left acute subdural haematoma.

Treatment:
Emergency craniotomy and evacuation of left temporal subdural haematoma
Post-operative care until patient condition is fit for discharge or transfer to rehabilitation or hospice care

Outcomes:
Patient did not recover cognitive function adequate to provide full medical history.
Welfare card in patient’s shirt pocket allowed identification of the patient to be established but inadequate for tracing of his medical or health care provider
Patient was discharged to State hospice service for ongoing care
Hospital EHRS allergy/intolerance list for this patient updated with “History of allergy or intolerance not asked – (patient is cognitively impaired)” information
Discharge summary sent to hospice service including “History of allergy or intolerance not asked – (patient is cognitively impaired)” information.

Use Case 13: Patient Documents Allergy in a PHR

Description
The purpose of this use case is to describe the review and update of an allergy list in a Personal Health Record by a patient

Conditions
The patient is part of a large integrated medical system with an electronic health care record and a tethered personal health record system allowing patients to view their own data from the electronic health record. The personal health record also has the capability of allowing patients to add their own data including weights, records of prescription and over-the-counter medications as well as other symptoms and health observations. Uploads of data from the
PHR do not occur unless the patient has a scheduled visit with a health care provider within the medical system.

**Exclusions**
Patient entered data is not uploaded into the EHR unless permission is provided by the patient.

**Preconditions**
Individual has had previous primary care physician who has created a list of allergies and intolerances that is part of the individual’s medical record and is now a part of the information provided in the personal health record.

**Use Case Sequence of Steps**
1. List of allergies and intolerances is downloaded into the patient’s PHR following the last visit to the primary care provider (PCP).
2. The patient logs into the PHR and views the list of allergies and intolerances as well as the current list of prescription medications and a history of laboratory tests.
3. Several weeks later the patient eats several cashews at a party. The patient notices about 10 minutes after eating the cashews, he has symptoms of an allergic reaction including mild hives and itching. The patient has not noticed a reaction to cashews in the past.
4. Upon returning home the patient adds the details of the reaction to the cashews to his PHR in the consumer health summary section.
5. Prior to visiting his PCP for an annual physical, the patient releases the data added to the PHR to be viewed by the PCP.
6. During the visit to the PCP a further review of the symptoms related to the ingestion of cashews confirms the diagnosis of an allergy to cashews.
7. The PCP adds the allergy to cashews to the allergy list in the EHR.
8. When the patient returns home and logs into the PHR, the allergy to cashews is now included on the allergy list.

**Post Condition**
Reconciled list of allergy and intolerances is part of patient electronic health record and personal health record.

**Use Case Scenario**
Adam Everyman is a 36 year old male who participates in a large integrated health care practice. As a service to patients, the personal health record, available through the health care practice portal provides Adam with the ability to review a copy of his electronic health record. The PHR also allows Adam to add data, text or images and can release the information he enters to any of the providers within the health care system on demand.

Adam is invited to a cocktail party where he eats several cashews. Several minutes after eating the nuts, Adam notices that he has an itchy mouth, hives, and feels like vomiting. The host gives Adam some Benadryl and the hives disappear. By the following morning the symptoms have subsided.
Adam logs into his PHR and notes in the allergy section, his symptoms related to eating the cashews. He also notes the onset and duration of symptoms and notes that he has not had any previous symptoms related to cashews, although he rarely eats them.

One month later, Adam has an appointment with his PCP. Prior to this visit, Adam allows the data he has entered into his PHR to be uploaded so that the PCP can see the data entered since the last visit. The PCP reviews the information provided by Adam in the PHR and asks Adam additional questions about his symptoms related to the episode as well as his history of any other food allergies. Following the review, the PCP concurs that Adam does have an allergy to cashews. The PCP documents an allergy to cashews as a new condition on Adam’s allergy list and advises Adam to not eat cashews in the future. When Adam logs into his PHR the following week, he finds that cashews now appear on his list of allergies and intolerances.

Use Case 14: Patient Reported Preferences

Description:
The purpose of this case is to demonstrate the documentation of patient preferences in the electronic health record (as differentiated from allergy and intolerance records)

Conditions:
• Patient prefers not to eat broccoli – no intolerance but she does not like the taste
• Patient has no documented food allergies or intolerances
• Patient has no documented medication allergies
• Patient prefers ibuprofen to acetaminophen for pain management
• The patient prefers not to receive epinephrine unless it is absolutely necessary for a medical emergency

Exceptions: none

Preconditions:
• Patient avoids broccoli when eating
• Patient uses ibuprofen at home for pain control

The patient used to live in the Southwest US, and as a college student was bitten by a scorpion. Due to a significant reaction to the bite, she was given an epinephrine (adrenaline) shot. Within seconds Eve experienced heart palpitations, nausea and tremors which subsided 30 minutes after the treatment. Eve has moved to a colder climate and has not had a subsequent need for epinephrine but is now concerned about the use of this drug in the hospital. Patient is scheduled for hip surgery and hospital admission

Use Case Sequence Steps:
1. Eve Everywoman a 52 year old female reports for her pre-surgical admission screening.
2. Eve completes a health history form where she marks broccoli, acetaminophen and adrenaline as allergies to ensure that she does not receive these while in the hospital.
3. Nancy Nightingale reviews the health history and follows up on non-routine responses.
4. Nancy Nightingale starts to record the broccoli allergy and requests additional information regarding history of this allergy and its symptoms and reactions.
5. Eve Everywoman indicates that she does not have a true food allergy to broccoli, but that she simply does not like it. (Negative preference)
6. Eve Everywoman also states that she is not allergic to acetaminophen but finds that ibuprofen is more effective for pain control. (Positive preference)
7. Eve reviews her history related to epinephrine. Eve insists that she is allergic to adrenaline. Nancy Nightingale discusses the possible need to use epinephrine in certain scenarios related to Eve’s care. (Preference with ability for provider to use with clinical judgment)
8. Nancy Nightingale records patient reported food and drug preferences within the medical record on the allergy and intolerance list.
9. When Eve Everywoman is admitted to the hospital, the patient preferences are shown on the allergy and intolerance list. They are noted as preferences. The diet request is forwarded to the food service department with the diet order and the NSAID preference is forwarded to the Pharmacy.
10. The epinephrine reaction and patient’s concerns are noted on the preference list.

Post Conditions:
1. Food service provides a diet without broccoli.
2. Ibuprofen is ordered instead of acetaminophen.
3. The use of epinephrine is not necessary but the past reaction is noted in the record.
4. Eve Everywoman has successful hip surgery and is discharged.
5. Patient preferences are documented in the EHR in/on the allergy and intolerance list as a preference.
6. Preferences are then transferred to Eve’s rehabilitation facility on discharge.

Actors
Patient - Eve Everywoman
Primary Care Physician - Dr. Patricia Primary
Hospital Attending - Dr. Aaron Attend
Registered Nurse - Nancy Nightingale

Use Case Scenario:

Eve Everywoman is scheduled for hip surgery at Good Health Hospital in a week. She reports for her pre-surgical physical at the hospital where she is asked to update her medical history. Nurse Nightingale reviews this history, noting the new allergies to broccoli, acetaminophen and epinephrine. She questions Eve regarding these allergies and learns that the broccoli and ibuprofen are preferences, not allergies or intolerances. Nurse Nightingale then marks avoidance of broccoli as a patient reported food preference and also documents the preference of ibuprofen over acetaminophen. This information is routed to the nutrition department and the pharmacy when Eve is admitted.
Eve states that she is quite sure she must be allergic to adrenaline and is most concerned about the use of epinephrine should a cardiac event occur during surgery. Dr. Aaron Attend speaks with Eve and notes that if necessary epinephrine will be used if medically indicated. However, Eve’s previous reaction will be noted in the medical record on the preference list.

After successful surgery, Eve is given ibuprofen-based pain medication. Eve is allowed a regular diet. Her food preference is noted and she does not receive broccoli. Henry Hamburger of the food service staff visits her and clarifies that she does not want broccoli.

Eve is discharged after surgery to a rehabilitation facility. Eve’s transition of care documents reflect documented preferences regarding pain management and food and her prior reaction to epinephrine.
Appendix A: Discussion of Criticality

By Dr Russ Leftwich

Severity and criticality are two related but distinct concepts in the domain of allergic and intolerance reactions.

Severity is an attribute of a symptom or a sign that is part of a reaction or an attribute of the constellation of signs and symptoms that constitute an episode of a reaction. Since there are a variety of different signs or symptoms and a variety of different reaction types, it would not be plausible to have a single rating scale that could be applied to different symptoms or two different types of reactions. It is true that rating scales have been established for research purposes to compare different episodes of a reaction type, such as anaphylaxis. It is also true that symptoms or reactions themselves are considered to have a range of severity and this is often divided intuitively into mild, moderate, and severe with mild and severe intuitively representing the two ends of the spectrum.

The list of allergies and intolerances for an individual is a list of conditions that represent a propensity to have a reaction if exposed to a specific substance in the future. This is based on a history of one or more past reactions. The potential seriousness of a future reaction is an attribute referred to as criticality. 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.

Although the list of allergies and intolerances for an individual might refer to a severe penicillin allergy or severe bee sting allergy, and the meaning is clear, this is not appropriate from a modeling standpoint. The model breaks down when the reaction type is not the presumed anaphylactic reaction of the penicillin allergy or the bee sting allergy.

As an example to contrast severity and criticality, an individual might have severe vomiting as an intolerance reaction for sulfa drugs. This reaction would be listed as a sulfa drug intolerance with low criticality, since the potential for serious injury from this is low. An individual who had a reaction immediately after a bee sting consisting of generalized itching, hives, and wheezing, which resolved without treatment would be considered to have had a mild anaphylactic episode. That individual's condition of anaphylactic sensitivity to bee stings would be considered of high criticality, because of the life-threatening potential.

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.
A scale or rating system for criticality does not seem plausible. It is a clinical judgment. When a group of practicing allergists were assembled to comment on stage 2 of Meaningful Use, their recommendation was that the allergy list should carry an attribute indicating criticality as to whether the condition was life-threatening or organ system threatening, or not.

If either a scale of criticality or severity that applied across different reaction types had been published in the literature, which I have not been able to find, it would not seem reasonable to expect this to be applied in clinical practice since the majority of clinicians would not be familiar with such a scale.

References:
http://www.medicines.org.uk/guides/leflunomide/rheumatoid%20arthritis
(information last updated 20 June 2012)
(information last updated 4 October 2010)

Definitions:
Criticality: of, relating to, or being a turning point or specially important juncture <a critical phase> as:
(1) relating to or being the stage of a disease at which an abrupt change for better or worse may be expected; also: being or relating to an illness or condition involving danger of death <critical care> <a patient listed in critical condition>
(2) relating to or being a state in which or a measurement or point at which some quality, property, or phenomenon suffers a definite change <critical temperature>
http://www.merriam-webster.com/dictionary/critical

Criticality level: indicates the tolerability of certain condition/illness; measure of the potential risks or danger that may be caused/resulted from the condition or change of condition.

Extensive literature search leads to identification of large body of publications on criticality levels and criteria in IT or business domains.

Example of IT criticality levels for business organizations:
Level 1: low dependence of IT; scheduled and unscheduled downtime is considered tolerable inconvenience
Level 2: dependent on IT; scheduled downtime is considered tolerable inconvenience
Level 3: high dependence on IT; high cost of downtime
Level 4: business model entirely dependent on IT; extremely high cost of downtime

However, the literature search does not lead to identification of any literature on criticality assessment of clinical conditions, allergy and intolerance included.
## Appendix B: Storyboard Naming Standards

### Table 1 - Family

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**Glossary**

*A special thanks to Andre Boudreau, Canada for his tireless compilation and upkeep of this glossary.*

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<th>Term</th>
<th>Definition</th>
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<td>Adverse Drug Reaction (ADR)</td>
<td>“Adverse drug reaction” as defined in the Food and Drug Regulations means a noxious and unintended response to a drug, which occurs at doses normally used or tested for the diagnosis, treatment or prevention of a disease or the modification of an organic function.</td>
<td>HC</td>
<td>Health Canada: Guidance Document for Industry - Reporting Adverse Reactions to Marketed Health Products*, 2009. 5 Food and Drug Regulations, Part C, Division 1, General (C.01.001), C.R.C., c. 870. 6 Natural Health Products Regulations, Interpretation, C.R.C., SOR/2003-196.</td>
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<tr>
<td>Serious adverse drug reaction – Serious</td>
<td>“Serious adverse drug reaction” as defined in the Food and Drug Regulations means a noxious and unintended response to a drug that occurs at any dose and that requires in-patient hospitalization or prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability or incapacity, is life-threatening or results in death.</td>
<td>HC</td>
<td>Health Canada: Guidance Document for Industry - Reporting Adverse Reactions to Marketed Health Products*, 2009. 5 Food and Drug Regulations, Part C, Division 1, General (C.01.001), C.R.C., c. 870. 6 Natural Health Products Regulations, Interpretation, C.R.C., SOR/2003-196.</td>
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<tr>
<td>Adverse Drug Reaction (ADR)</td>
<td>A response to a pharmaceutical product which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for modification of physiological function.</td>
<td>UK national healthcare agency</td>
<td>Cited in: Design Guidance- Displaying Adverse Drug Reaction Risks- Microsoft- 28 January 2009 - Version 1.0.0.0, page 2</td>
</tr>
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</table>
The meaning of this expression differs from the meaning of "side effect", as this last expression might also imply that the effects can be beneficial.[2] The study of ADRs is the concern of the field known as pharmacovigilance.

**Pre-marketing**: All noxious and unintended responses to a medicinal

**Post-marketing/WHO**: A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for the modification of physiologic function.

**WHO**: Any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with this product.

**Post-marketing/US**: Any undesirable effect reasonably associated with the use of the drug, that may occur as part of the pharmacological action of the drug or may be unpredictable.

**Post-marketing/European Union**: A reaction which is harmful and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis, or treatment of disease or the modification of physiological function.

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**Adverse Drug Reaction (ADR)**

| Pre-marketing: All noxious and unintended responses to a medicinal |
| Post-marketing/WHO: A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for the modification of physiologic function. |
| WHO: Any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with this product. |
| Post-marketing/US: Any undesirable effect reasonably associated with the use of the drug, that may occur as part of the pharmacological action of the drug or may be unpredictable. |
| Post-marketing/European Union: A reaction which is harmful and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis, or treatment of disease or the modification of physiological function. |

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**Adverse Drug Reaction or Adverse Medication Reaction**

product related to any dose.

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http://www.hl7.org/documentcenter/public_temp_CB795262-1C23-BA17-0CB0EE75414D3DBA/calendarofevents/FirstTime/Glossary%20of%20terms.pdf

Master Glossary- March 16, 2009 - R02.04.00-HL7 v3 pan-Canadian Messaging Standards, Canada Health infoway
<p>| Adverse Effect/Adverse Experience | Adverse Effect | Post-marketing/WHO: A response to a drug which is noxious and | wikipedia |  |
|----------------------------------|---------------|-------------------------------------------------------------|-----------------|
| Adverse Event                    |               | unintended, and which occurs at doses normally used in man for | CDISC BRIDG 3.0.3 Comprehensive Domain Analysis Model - Static Elements Report - BRIDG Semantic Coordination Committee, CDISC, 16 Dec. 2010. |
| Adverse Event                    |               | prophylaxis, diagnosis, or therapy of disease or for the modification of | CDISC BRIDG 3.0.3 Comprehensive Domain Analysis Model - Static Elements Report - BRIDG Semantic Coordination Committee, CDISC, 16 Dec. 2010. |
| Adverse Event                    |               | physiologic function. | CHI Master Glossary- March 16, 2009 - R02.04.00-HL7 v3 pan-Canadian Messaging Standards, Canada Health infoway |
| Adverse Event                    |               | WHO: Any untoward medical occurrence that may present during | NCI/NIH USA Common Terminology Criteria for Adverse Events (CTCAE) - Version 4.0, Page Published: May 28, 2009 (v4.03: June 14, 2010) U.S.DEPARTMENT OF HEALTH AND HUMAN SERVICES, National Institutes of Health, National Cancer Institute |
| Adverse Event/Adverse Experience |               | Pre-marketing: Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. Post-marketing/US: Any adverse event associated with the use of a drug in humans, whether or not considered drug related, including the following: An adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose; an adverse event occurring from drug withdrawal; and any failure of expected pharmacologic action. Post-marketing/European Union: Any undesirable experience occurring to a patient treated with a pharmaceutical product | HL7 <a href="http://www.hl7.org/documentcenter/public_temp_CB795262-1C23-BA17-0CB0EE75414D3DBA/calendarofevents/FirstTime/Glossary%20of%20terms.pdf">http://www.hl7.org/documentcenter/public_temp_CB795262-1C23-BA17-0CB0EE75414D3DBA/calendarofevents/FirstTime/Glossary%20of%20terms.pdf</a> |</p>
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<tr>
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<th>treatment with a pharmaceutical product but which does not</th>
<th>CHI</th>
<th>Master Glossary- March 16, 2009 - R02.04.00-HL7 v3 pan-Canadian Messaging Standards, Canada Health infoway</th>
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<tbody>
<tr>
<td>Adverse Reaction</td>
<td>Indicates that the observation is of an unexpected negative occurrence in the subject suspected to result from the subject's exposure to one or more agents. Observation values would be the symptom resulting from the reaction.</td>
<td>UMLS</td>
<td>SNOMED CT TERM: Concept 282100009 Adverse reaction to a substance</td>
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<tr>
<td>Adverse Reaction (AR)</td>
<td>necessarily have a causal relationship with this product.</td>
<td>HC</td>
<td>Health canada: Guidance Document for Industry - Reporting Adverse Reactions to Marketed Health Products*, 2009. 5 Food and Drug Regulations, Part C, Division 1, General (C.01.001), C.R.C., c. 870. 6 Natural Health Products Regulations, Interpretation, C.R.C., SOR/2003-196.</td>
</tr>
<tr>
<td>Adverse Reaction (AR)</td>
<td>the use of the drug, that may occur as part of the pharmacological</td>
<td>CHI</td>
<td>Master Glossary- March 16, 2009 - R02.04.00-HL7 v3 pan-Canadian Messaging Standards, Canada Health infoway</td>
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<tr>
<td>Adverse Reaction (AR)</td>
<td>action of the drug or may be unpredictable.</td>
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<td>Post-marketing/European Union: A reaction which is harmful and</td>
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<td>Adverse Reaction - Serious</td>
<td>prophylaxis, diagnosis, or treatment of disease or the modification of</td>
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<tr>
<td>Adverse Reaction - Serious</td>
<td>physiological function.</td>
<td>HC</td>
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<td>Adverse Substance Reaction</td>
<td>A harmful or undesirable effect associated with exposure to any substance or agent, including food, plants, animals, venom from animal stings or a medication at therapeutic or sub-therapeutic doses. Synonymous names: Allergic reactions, Allergies</td>
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<td>Alert</td>
<td>See Contraindication Alert. Source: CeRx</td>
<td>CHI</td>
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<td>Allergen</td>
<td>An antigenic substance capable of producing immediate type of hypersensitivity reaction (allergy). Note: this term is under review</td>
<td>CHI</td>
<td></td>
</tr>
<tr>
<td>Allergen</td>
<td>An allergen is a substance that can cause an allergic reaction. Allergens are substances that, in some people, the immune system recognizes as &quot;foreign&quot; or &quot;dangerous&quot; but cause no response for most people.</td>
<td>CHI</td>
<td></td>
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<tr>
<td><strong>Allergic drug reaction</strong></td>
<td>A response to a pharmaceutical product to which an individual has become sensitised, in which histamine, serotonin and other vasoactive substances are released, in response to an immune system-mediated reaction. This causes systemic symptoms which can include pruritus, erythema, flushing, urticaria, angio-oedema, nausea, diarrhoea, vomiting, laryngeal oedema, bronchospasm, hypotension, cardiovascular collapse and death.</td>
<td>Cited in: Design Guidance- Displaying Adverse Drug Reaction Risks- Microsoft- 28 January 2009 - Version 1.0.0.0, page 2</td>
<td></td>
</tr>
<tr>
<td><strong>Allergic reaction</strong></td>
<td>Allergic reactions are sensitivities to substances, called allergens, that come into contact with the skin, nose, eyes, respiratory tract, and gastrointestinal tract. They can be inhaled into the lungs, swallowed, or injected. Many allergic reactions are mild, while others can be severe and life-threatening. They can be confined to a small area of the body, or they may affect the entire body. The most severe form is called anaphylaxis or anaphylactic shock.... Anaphylaxis is a sudden and severe allergic reaction that occurs within minutes of exposure. Immediate medical attention is needed for this condition. Without treatment, anaphylaxis can get worse very quickly and lead to death within 15 minutes.</td>
<td>MedlinePlus Medical Encyclopedia. A service of the U.S. National Library of Medicine, National Institutes of Health, USA</td>
<td></td>
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<tr>
<td><strong>Allergy</strong></td>
<td>Hypersensitivity caused by exposure to a particular antigen (allergen) resulting in a marked increase in reactivity to that antigen upon</td>
<td>CHI Master Glossary- March 16, 2009 - R02.04.00-HL7 v3 pan-Canadian Messaging Standards, Canada Health Infoway</td>
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subsequent exposure, sometimes resulting in harmful immunologic consequences. Note: this term is under review

<table>
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<th>Allergy</th>
<th>A hypersensitivity caused by an exposure to an antigen which results in an adverse immunologic reaction on subsequent exposures</th>
<th>CHI</th>
<th>Shared Health Record (SHR)</th>
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<tr>
<td>Allergy</td>
<td>An allergy is a hypersensitivity caused by an exposure to an antigen which results in an adverse immunologic reaction on subsequent exposures e.g. immunologic reactions such as rash, hives, swelling and anaphylaxis such as having been tested and determined to be allergic to penicillin.</td>
<td>CHI pCS</td>
<td>HL7 v3 pan-Canadian Messaging Standards - Implementation Guide Volume 8 - Pharmacy, Canada Health Infoway, March 26, 2010 R02.04.02, page 72</td>
</tr>
<tr>
<td>Allergy</td>
<td>The <code>&lt;code&gt;</code> element represents the kind of allergy observation made, to a drug, food or environmental agent, and whether it is an allergy, non-allergy intolerance, or unknown class of intolerance (not known to be allergy or intolerance). The example above uses the HL7 ObservationIntoleranceType vocabulary domain, which does provide suitable observation codes. Other vocabularies may be used, such as SNOMED-CT or MEDCIN. The <code>&lt;value&gt;</code> is a description of the allergy or adverse reaction.</td>
<td>IHE</td>
<td>IHE_PCC_Care_Management_CM_Supplement_TL_2008-08-22.pdf</td>
</tr>
<tr>
<td>Allergy</td>
<td>Allergy is defined by an immunological hypersensitivity to one or several defined antigens, called allergens, which trigger symptoms in the skin, the upper or lower airways, or the oral and digestive mucosae upon exposure, according to the mechanisms and the target organ(s) involved.</td>
<td></td>
<td>PHYSIOPATHOLOGY OF ALLERGY, by Charles PILETTE, MD, Pneumology Department, St-Luc University Hospital and Pneumology Unit, University of Louvain (UCL), Brussels - Belgium. © UCB IOA and Prof. Dr. C. Pilette – May 2008</td>
</tr>
<tr>
<td>Allergy</td>
<td>An allergy is an exaggerated immune response or reaction to substances that are generally not harmful. The immune response is how your body recognizes and defends itself against bacteria, viruses, and substances that appear foreign and harmful. The immune system protects the body from potentially harmful substances by recognizing and responding to antigens.</td>
<td>MedlinePlus Medical Encyclopedia. A service of the U.S. National Library of Medicine, National Institutes of Health, USA</td>
<td></td>
</tr>
<tr>
<td>---</td>
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<td></td>
</tr>
<tr>
<td>Allergy</td>
<td>Allergies occur when your immune system reacts to a foreign substance such as pollen, bee venom or pet dander. See also anaphylaxis. Your immune system produces substances known as antibodies. Some of these antibodies protect you from unwanted invaders that could make you sick or cause an infection. When you have allergies, your immune system makes antibodies that identify your particular allergen as something harmful, even though it isn't. When you come into contact with the allergen, your immune system's reaction inflames your skin, sinuses, airways or digestive system. The severity of allergies varies from person to person and can range from minor irritation to anaphylaxis — a potentially life-threatening emergency. While allergies can't be cured, a number of treatments can help relieve your allergy symptoms.</td>
<td>Mayo Clinic Staff <a href="http://www.mayoclinic.com/health/allergies/DS01118">http://www.mayoclinic.com/health/allergies/DS01118</a></td>
<td></td>
</tr>
<tr>
<td>Allergy</td>
<td>Medicine net</td>
<td></td>
<td></td>
</tr>
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<td>---------</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>An allergy refers to an exaggerated reaction by our immune system in response to bodily contact with certain foreign substances. It is exaggerated because these foreign substances are usually seen by the body as harmless and no response occurs in non-allergic people. Allergic people's bodies recognize the foreign substance and one part of the immune system is turned on. Allergy-producing substances are called &quot;allergens.&quot; When an allergen comes in contact with the body, it causes the immune system to develop an allergic reaction in persons who are allergic to it. When you inappropriately react to allergens that are normally harmless to other people, you are having an allergic reaction and can be referred to as allergic or atopic. Therefore, people who are prone to allergies are said to be allergic or &quot;atopic.&quot;</td>
<td><a href="http://www.medicinenet.com/allergy/article.htm">http://www.medicinenet.com/allergy/article.htm</a></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Allergy</th>
<th>wikipedia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allergy is a hypersensitivity disorder of the immune system.[1] Allergic reactions occur to normally harmless environmental substances known as allergens; these reactions are acquired, predictable, and rapid. Strictly, allergy is one of four forms of hypersensitivity and is called type I (or immediate) hypersensitivity. It is characterized by excessive activation of certain white blood cells called mast cells and basophils by a type of antibody known as IgE, resulting in an extreme inflammatory response. Common allergic reactions include eczema, hives, hay fever, asthma attacks, food allergies, and reactions to the venom of stinging insects such as wasps and bees.[2] Allergy types: Allergic rhinitis, asthma,</td>
<td><a href="http://en.wikipedia.org/wiki/Allergy1.-">http://en.wikipedia.org/wiki/Allergy1.-</a> allergy at Dorland's Medical Dictionary2.- Kay AB (2000). &quot;Overview of 'allergy and allergic diseases: with a view to the future'.&quot; Br. Med. Bull. 56 (4): 843–64. doi:10.1258/0007142001903481. PMID 11359624.</td>
</tr>
<tr>
<td>Allergy</td>
<td>atopic eczema, anaphylaxis, insect venom, drug allergies, food allergies, multiple allergies (Asthma, eczema and allergic rhinitis together).</td>
</tr>
<tr>
<td>---------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Allergy- Anaphylaxis</td>
<td>1 : altered bodily reactivity (as hypersensitivity) to an antigen in response to a first exposure &lt;his bee-venom allergy may render a second sting fatal&gt; 2 : exaggerated or pathological reaction (as by sneezing, respiratory embarrassment, itching, or skin rashes) to substances, situations, or physical states that are without comparable effect on the average individual</td>
</tr>
<tr>
<td>Allergy Confirmation Indicator</td>
<td>Specifies that an act statement is made with or without an assertion of uncertainty. Codes used in conveying to other Health Service Providers, the level of confidence to be placed in a</td>
</tr>
</tbody>
</table>

**Anaphylaxis**

Anaphylaxis is a serious allergic reaction that involves more than one organ system (for example, skin and respiratory tract, and/or gastrointestinal tract), can begin very rapidly, and can cause death. **Causes** The leading cause of anaphylaxis is food allergy, especially allergy to peanut and tree nuts; however, medications like penicillin, insect stings, and latex can also cause an allergic reaction that leads to anaphylaxis. **Symptoms** Anaphylaxis includes a wide range of symptoms that can occur in many combinations and be difficult to recognize. Some symptoms are not life-threatening, but the most severe ones restrict breathing and blood circulation.

**NIAID**

National Institute of Allergy and Infectious Diseases, National Institutes of Health, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES http://www.niaid.nih.gov/topics/allergicDiseases/Pages/Anaphylaxis.aspx

**CHI**

Infoway Master Terminology Worksheet (MTW)
| **Allergy - Drug** | Drug allergies are a group of symptoms caused by an allergic reaction to a drug (medication).

Adverse reactions to drugs are common, and almost any drug can cause an adverse reaction. Reactions range from irritating or mild side effects such as nausea and vomiting to life-threatening anaphylaxis. A true drug allergy results from a series of chemical steps within the body that produce the allergic reaction to a medication. | MedlinePlus Medical Encyclopedia. A service of the U.S. National Library of Medicine, National Institutes of Health, USA |
| **Allergy - Food** | Food allergy is an abnormal response to a food, triggered by the body's immune system. There are several types of immune responses to food. The information on this Web site focuses on one type of adverse reaction to food, in which the body produces a specific type of antibody, called immunoglobulin E (IgE). The binding of IgE antibodies to specific molecules in a food triggers the immune response. Read about what happens during an allergic response to food. The response may be mild, or in rare cases it can be associated with the severe and life-threatening reaction called anaphylaxis. Sometimes, a reaction to food is not an allergy at all but another type of reaction called food intolerance. | NIAID Food Allergy - An Overview, Nov. 2010 National Institute of Allergy and Infectious Diseases, National Institutes of Health, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES http://www.niaid.nih.gov/topics/foodAllergy/understanding/Pages/whatIsIt.aspx |
| **Allergy - Food** | Food allergy is an abnormal response to a food triggered by your body's immune system. Allergic reactions to food can sometimes cause serious illness and death. Tree nuts and peanuts are the leading causes of deadly allergic reactions called anaphylaxis. | MedlinePlus Medical Encyclopedia. A service of the U.S. National Library of Medicine, National Institutes of Health, USA |
Sometimes a reaction to food is not an allergy. It is often a reaction called "food intolerance". Your immune system does not cause the symptoms of food intolerance. However, these symptoms can look and feel like those of a food allergy.

### Allergy- Food

Food allergy is an immune system reaction that occurs soon after eating a certain food. Even a tiny amount of the allergy-causing food can trigger signs and symptoms such as digestive problems, hives or swollen airways. In some people, a food allergy can cause severe symptoms or even a life-threatening reaction known as anaphylaxis.

- **Definition by Mayo Clinic staff**

True allergic reactions to food involve the body's immune system. When the body identifies a food as harmful, it produces antibodies directed against that food. The next time the food is consumed, the body mounts an immune response with the release of histamine and other chemicals that trigger allergic symptoms. A common example of a food allergy is to peanuts. With a food allergy, symptoms may occur almost immediately or up to hours after consuming the particular food. These symptoms may affect the respiratory system, gastrointestinal tract, cardiovascular system, or the skin.

- **medicine.net**

### Allergy Test Result Code

- Indicates the result of a particular allergy test

### Allergy Test Type

- Indicates the type of allergy test performed.
<table>
<thead>
<tr>
<th>Allergy/Intolerance</th>
<th>Represents the specific allergen or other agent/substance to which the Client has an allergic reaction or intolerance.</th>
<th>CIHI</th>
<th>Draft Pan-Canadian Primary Health Care Electronic Medical Record Content, Version 2 Standard Implementation Guide (Ottawa, Ont.: CIHI, 2010) (pdf). Canadian Institute for Health Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category</td>
<td>Codes for different categorizations of reactions. E.g. &quot;Allergy&quot;, &quot;Intolerance&quot;, etc.</td>
<td>CHI</td>
<td>Infoway Master Terminology Worksheet (MTW)</td>
</tr>
<tr>
<td>Severity</td>
<td>Represents the level of severity a Client has in relation to an allergy or intolerance.</td>
<td>CIHI</td>
<td>Draft Pan-Canadian Primary Health Care Electronic Medical Record Content, Version 2 Standard Implementation Guide (Ottawa, Ont.: CIHI, 2010) (pdf). Canadian Institute for Health Information</td>
</tr>
<tr>
<td>Date of Onset</td>
<td>Represents the date of onset associated with the Client's allergy or intolerance. IG: Represents the date on which the recorded allergy/intolerance is considered active.</td>
<td>CIHI</td>
<td>Draft Pan-Canadian Primary Health Care Electronic Medical Record Content, Version 2 Standard Implementation Guide (Ottawa, Ont.: CIHI, 2010) (pdf). Canadian Institute for Health Information</td>
</tr>
<tr>
<td>Type</td>
<td>Represents the type of allergy or intolerance a Client has.</td>
<td>CIHI</td>
<td>Draft Pan-Canadian Primary Health Care Electronic Medical Record Content, Version 2 Standard Implementation Guide (Ottawa, Ont.: CIHI, 2010) (pdf). Canadian Institute for Health Information</td>
</tr>
<tr>
<td>Anaphylaxis</td>
<td>Anaphylaxis is a severe, potentially life-threatening allergic reaction. It can occur within seconds or minutes of exposure to something you're allergic to, such as the venom from a bee sting or a peanut. The flood of chemicals released by your immune system during anaphylaxis can cause you to go into shock; your blood pressure drops suddenly and your airways narrow, blocking normal breathing.</td>
<td>Mayo</td>
<td>Definition by Mayo Clinic staff <a href="http://www.mayoclinic.com/health/anaphylaxis/DS00009">http://www.mayoclinic.com/health/anaphylaxis/DS00009</a></td>
</tr>
</tbody>
</table>

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Page 62 Patient Care WG Allergy and Intolerance Domain Analysis Model (Informative) © 2013 Health Level Seven International. All rights reserved. January 2013 Ballot Cycle
<table>
<thead>
<tr>
<th>Breathing. Signs and symptoms of anaphylaxis include a rapid, weak pulse, a skin rash, and nausea and vomiting. Common triggers of anaphylaxis include certain foods, some medications, insect venom and latex. Anaphylaxis requires an immediate trip to the emergency department and an injection of epinephrine. If anaphylaxis isn't treated right away, it can lead to unconsciousness or even death.</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Information</td>
<td>Refers to the data contained in the patient record. The data may include such things as problem lists, lab results, current medications, family history, etc. For the purposes of this chapter, clinical information is limited to diagnoses (DG1), results reported (OBX/OBR), and allergies (AL1).</td>
</tr>
<tr>
<td>Merriuam Webster and UMLS</td>
<td><a href="http://www.hl7.org/documentcenter/public_temp_CB795262-1C23-BA17-0CB0EE75414D3DBA/calendarofevents/FirstTime/Glossary%20of%20terms.pdf">http://www.hl7.org/documentcenter/public_temp_CB795262-1C23-BA17-0CB0EE75414D3DBA/calendarofevents/FirstTime/Glossary%20of%20terms.pdf</a></td>
</tr>
<tr>
<td>Condition</td>
<td>A state of being or a usually defective state of health conditions</td>
</tr>
<tr>
<td>Merriuam Webster and UMLS</td>
<td><a href="http://www.merriam-webster.com/dictionary/condition">http://www.merriam-webster.com/dictionary/condition</a> SNOMED CT TERM: concept 26095004 - Condition -- a qualitative concept</td>
</tr>
<tr>
<td>Contraindication</td>
<td>A contraindication is any physical condition, current medication or other factor that indicates that a person should not receive an immunization that may be associated with the contraindication. This contraindication may be temporary or permanent. LOINC: 30945-0 There are a number of contraindications to immunization. These may be temporary or permanent. One is a history of reactions to previous immunization. That is dealt with above. Others include allergies to components of vaccines,</td>
</tr>
<tr>
<td></td>
<td>HL7 Version 2.5.1 Implementation Guide for Immunization Messaging, Release 1.2, 2011-02-15, (255 pages) Immunization Information Systems Support Branch, Immunization Services Division, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention (US dept of Health and Human Services), and American Immunization Registry Association</td>
</tr>
<tr>
<td><strong>physical conditions, current medication and current illnesses.</strong></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td></td>
</tr>
<tr>
<td><strong>Criticality</strong></td>
<td>Criticality: of, relating to, or being a turning point or specially important juncture &lt;a critical phase&gt; as: (1) relating to or being the stage of a disease at which an abrupt change for better or worse may be expected; also: being or relating to an illness or condition involving danger of death &lt;critical care&gt; &lt;a patient listed in critical condition&gt; (2) relating to or being a state in which or a measurement or point at which some quality, property, or phenomenon suffers a definite change &lt;critical temperature&gt;</td>
</tr>
<tr>
<td><strong>Mirriam Webster</strong></td>
<td><a href="http://www.merriam-webster.com/dictionary/critical">http://www.merriam-webster.com/dictionary/critical</a></td>
</tr>
<tr>
<td><strong>Device</strong></td>
<td>See Medical Device</td>
</tr>
<tr>
<td><strong>Diet</strong></td>
<td>A diet consists of the diet codes, supplements, and preferences effective at a given time. These three specifications govern which foods a patient will receive. Diets generally do not have a stated ending time to ensure that the patient always receives food.</td>
</tr>
<tr>
<td><strong>Domain Analysis Model (DAM)</strong></td>
<td>The analysis of a particular topic or domain.</td>
</tr>
<tr>
<td><strong>Drug</strong></td>
<td>Any chemical compound that may be used on or administered to humans or animals as an aid in the diagnosis, treatment or prevention of disease or other abnormal</td>
</tr>
<tr>
<td><strong>Drug Intolerance</strong></td>
<td>See Intolerance. Source: CeRx</td>
</tr>
<tr>
<td>----------------------</td>
<td>--------------------------------</td>
</tr>
<tr>
<td><strong>Drug Intolerance</strong></td>
<td>A response to a pharmaceutical product which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for modification of physiological function</td>
</tr>
<tr>
<td><strong>Drug Intolerance</strong></td>
<td>An undesirable effect produced by the pharmacological actions of a pharmaceutical product at therapeutic or subtherapeutic dosages and which prevents the patient from tolerating treatment with that product.</td>
</tr>
<tr>
<td><strong>Drug-Drug Interactions</strong></td>
<td>See definition for Drug Interactions. Source: Lab</td>
</tr>
<tr>
<td><strong>Health Care Provider</strong></td>
<td>Refers to a person licensed, certified or otherwise authorized or permitted by law to administer health care in the ordinary course of business or practice of a profession, including a health care facility.</td>
</tr>
<tr>
<td><strong>Health Condition</strong></td>
<td>Symptoms, health problems (not yet diagnosed), diagnoses (known or provisional) and physiologic changes that affect the body as a whole or one or more of its parts (such as diabetes), and/or affect the personís well-being (such as psychosis), and/or affect the personís usual physiological state (such as pregnancy, lactation). Source: iEHR</td>
</tr>
<tr>
<td>Hypersensitivity</td>
<td>Altered reactivity to an antigen, which can result in pathologic reactions upon subsequent exposure to that particular antigen. (Scope Note).</td>
</tr>
<tr>
<td>------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Hypersensitivity</td>
<td>Hypersensitivity (also called hypersensitivity reaction) refers to undesirable reactions produced by the normal immune system. These reactions may be damaging, uncomfortable, or occasionally fatal. Hypersensitivity reactions require a pre-sensitized (immune) state of the host. The four-group classification was expounded by P. H. G. Gell and Robin Coombs in 1963</td>
</tr>
<tr>
<td>Intolerance</td>
<td>Inability to withstand or to tolerate, sensitivity, as to a drug. Source: CeRx</td>
</tr>
<tr>
<td>Intolerance</td>
<td>Any identified intolerance that is caused by a mechanism other than an immunologic over-response</td>
</tr>
<tr>
<td>Intolerance</td>
<td>An intolerance is any identified intolerance which is caused by a mechanism other than immunologic over-response e.g. nausea, dry mouth, hair loss. An example would be nausea if taking erythromycin with an allergy having been ruled out.</td>
</tr>
<tr>
<td>Intolerance</td>
<td>Inability to withstand or consume; inability to absorb or metabolize nutrients</td>
</tr>
<tr>
<td>Intolerance</td>
<td>Intolerance, a synonym of sensitivity (physiology) * Drug intolerance * Food intolerance * Lactose intolerance * Hereditary fructose intolerance * Sucrose intolerance * Lysinuric protein intolerance * Citric acid intolerance * Salicylate intolerance, also known as aspirin intolerance * Lysinuric protein intolerance * Cold intolerance</td>
</tr>
</tbody>
</table>
### Intolerance

**Orthostatic intolerance**

**Exercise intolerance**

NOTE: the concept of intolerance seems to be included in the Allergy concept in MedlinePlus. However, Intolerance is used in combination with other concepts, e.g. Lactose Intolerance, Gluten Intolerance.

<table>
<thead>
<tr>
<th>Intolerance - Food (1 of 2)</th>
</tr>
</thead>
</table>

**Lactose intolerance:**
Lactose is a sugar found in milk and most milk products. Lactase is an enzyme in the lining of the gut that breaks down or digests lactose. Lactose intolerance occurs when lactase is missing. Instead of the enzyme breaking down the sugar, bacteria in the gut break it down, which forms gas, which in turn causes symptoms of bloating, abdominal pain, and sometimes diarrhea.

**Food additives:**
Another type of food intolerance is a reaction to certain products that are added to food to enhance taste, add color, or protect against the growth of microbes. Compounds such as monosodium glutamate (MSG) and sulfites are tied to reactions that can be confused with food allergy.

**Gluten intolerance:**
Gluten is a part of wheat, barley, and rye. Gluten

MedlinePlus Medical Encyclopedia. A service of the U.S. National Library of Medicine, National Institutes of Health, USA

Food Allergy - An Overview, Nov. 2010
National Institute of Allergy and Infectious Diseases, National Institutes of Health, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
http://www.niaid.nih.gov/TOPICS/FOODALLERGY/UNDERSTANDING/Pages/foodIntolerance.aspx

NIAID
<p>| Intolerance - Food (2 of 2) | Food poisoning: Some of the symptoms of food allergy, such as abdominal cramping, are common to food poisoning. However, food poisoning is caused by microbes, such as bacteria, and bacterial products, such as toxins, that can contaminate meats and dairy products. Histamine toxicity: Fish, such as tuna and mackerel that are not refrigerated properly and become contaminated by bacteria, may contain very high levels of histamine. A person who eats such fish may show symptoms that are similar to food allergy. However, this reaction is not a true allergic reaction. Instead, the reaction is called histamine toxicity or scombroid food poisoning. Other conditions: Several other conditions, such as ulcers and cancers of the gastrointestinal (GI) tract, cause some of the same symptoms as food allergy. These symptoms, which include vomiting, diarrhea, and cramping abdominal pain, become worse when you eat. | NIAID | Food Allergy - An Overview, Nov. 2010 National Institute of Allergy and Infectious Diseases, National Institutes of Health, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES <a href="http://www.niaid.nih.gov/TOPICS/FOODALLERGY/UNDERSTANDING/Pages/foodIntolerance.aspx">http://www.niaid.nih.gov/TOPICS/FOODALLERGY/UNDERSTANDING/Pages/foodIntolerance.aspx</a> |</p>
<table>
<thead>
<tr>
<th>Intolerance - Food</th>
<th>Food intolerance is different from food allergy in that it does not involve an immunologic reaction. A common type of food intolerance is lactose intolerance. Persons with lactose intolerance lack an enzyme (called lactase) needed to digest the milk sugar (called lactose). They can develop gas, bloating, and abdominal pain when they consume milk products. Some types of food intolerance can be treated. For example, lactase tablets are available without a prescription to aid those with severe symptoms of lactose intolerance and lactose-free dairy products are available at most supermarkets.</th>
<th>medicine.net</th>
<th><a href="http://www.medicinenet.com/script/main/art.asp?articlekey=43471">http://www.medicinenet.com/script/main/art.asp?articlekey=43471</a></th>
</tr>
</thead>
<tbody>
<tr>
<td>Intolerance Agent</td>
<td>Codes identifying allergens and other agents which cause allergies and intolerances.</td>
<td>CHI</td>
<td>Infoway Master Terminology Worksheet (MTW)</td>
</tr>
<tr>
<td>Intolerance - Substance</td>
<td>A sensitivity to a substance or category of substances, such that exposure to the substance is likely to result in an adverse reaction AND where it has not been possible to identify with any degree of certainty which type of adverse reaction it is. Allergies and intolerances are generally differentiated based on the type of reaction: • immunologic reactions such as rash, hives, swelling, and anaphylaxis generally signify the presence of an allergy; • other reactions such as nausea, dry mouth, hair loss, etc. would qualify as intolerances. Because allergens are immunologic in nature, they have a risk of producing an increased severity reaction on subsequent exposures. Intolerances do not tend to have such a risk. Because of this distinction, an alert can be considered.</td>
<td>HL7</td>
<td>HL7 CIC NCRI WG-2011-05-19</td>
</tr>
<tr>
<td>Intolerance - Uncategorized</td>
<td></td>
<td>CHI</td>
<td>Shared Health Record (SHR)</td>
</tr>
<tr>
<td>Intolerance- Uncategorized</td>
<td>Both Allergies and Intolerances are types of an ‘Uncategorized Intolerance’ (where the category has been determined).</td>
<td>CHI pCS</td>
<td>HL7 v3 pan-Canadian Messaging Standards - Implementation Guide Volume 8 - Pharmacy, Canada Health Infoway, March 26, 2010 R02.04.02, page 72</td>
</tr>
<tr>
<td>----------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------</td>
<td>-------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Intolerance- Unclassified</td>
<td>It has been noted that many ‘unclassified intolerances’ may be recorded as an intolerance rather than allergy. With an ‘unclassified intolerance’, a provider believes that there has been/ may be an adverse response to an identifiable product - a sensitivity to a substance or category of substances, such that exposure to the substance is likely to result in an adverse reaction and where it has either not been possible to identify with any degree of certainty which type of adverse reaction it is or no additional effort has been made to definitively determine if the sensitivity is an intolerance or allergy.</td>
<td>CHI pCS</td>
<td>HL7 v3 pan-Canadian Messaging Standards - Implementation Guide Volume 8 - Pharmacy, Canada Health Infoway, March 26, 2010 R02.04.02, page 72</td>
</tr>
<tr>
<td>Issue Trigger Observation Coded Type</td>
<td>Distinguishes the kinds of coded observations that could be the trigger for clinical issue detection. These are observations that are not measurable, but instead can be defined with codes. Coded observation types include: Allergy, Intolerance, Medical Condition, Pregnancy status, etc.</td>
<td>CHI Infoway Master Terminology Worksheet (MTW)</td>
<td></td>
</tr>
<tr>
<td>Issue Trigger Observation Value</td>
<td>The combined domain for different types of coded observation issue triggers, such as diagnoses, allergies, etc.</td>
<td>CHI Infoway Master Terminology Worksheet (MTW)</td>
<td></td>
</tr>
<tr>
<td>Issue Type</td>
<td>Definition</td>
<td>Source</td>
<td>Reference</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-------------------------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Medical Condition</td>
<td>A state of health. A disease or physical ailment: a heart condition.</td>
<td>CHI</td>
<td>Master Glossary- March 16, 2009 - R02.04.00-HL7 v3 pan-Canadian Messaging Standards, Canada Health infoway</td>
</tr>
<tr>
<td>Medical Device</td>
<td>Something contrived for or used in the diagnosis (vascular catheters), treatment (thermotherapy units) or prevention of disease or other abnormal condition, for the relief of pain or suffering or to control or improve any physiologic condition, including instrumentation and implanted devices (prosthetic cardiac valves, pacemakers, hip prostheses).</td>
<td>HL7</td>
<td><a href="http://www.hl7.org/documentcenter/public_temp_CB795262-1C23-BA17-0CB0EE75414D3DBA/calendarofevents/FirstTime/Glossary%20of%20terms.pdf">http://www.hl7.org/documentcenter/public_temp_CB795262-1C23-BA17-0CB0EE75414D3DBA/calendarofevents/FirstTime/Glossary%20of%20terms.pdf</a></td>
</tr>
<tr>
<td>Medication Incident</td>
<td>Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Medication incidents may be related to professional practice, drug products, procedures, and systems, and include prescribing, order communication, product labelling/packaging/nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.</td>
<td>CHI</td>
<td>Master Glossary- March 16, 2009 - R02.04.00-HL7 v3 pan-Canadian Messaging Standards, Canada Health infoway</td>
</tr>
<tr>
<td>Medication Misadventure</td>
<td>A hazard or incident that: • is an inherent risk when medication therapy is indicated, • is created through either omission or commission by the administration of a medicine or medicines during which a patient may be harmed, with effects ranging from mild</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| CHI | Infoway Master Terminology Worksheet (MTW) |
| **discomfort to fatality,**  
| • whose outcome may or may not be independent of the pre-existing pathology or disease process,  
| • may be attributable to incident (human or system or both), immunologic response, or idiosyncratic response,  
| • is always unexpected or undesirable to the patient and health professional.  
| **Source:** CeRx |

| **Non-Drug Agent**  
| Indicates types of allergy and intolerance agents which are non-drugs. (E.g. foods, latex, etc.)  
| **CHI**  
| **Infoway Master Terminology Worksheet (MTW)** |

| **Non-Drug Intolerance**  
| See definition for Intolerance. **Source:** CeRx  
| **CHI**  
| **Master Glossary- March 16, 2009 - R02.04.00-HL7 v3 pan-Canadian Messaging Standards, Canada Health infoway** |

| **Paradoxical reaction**  
| A paradoxical reaction or paradoxical effect is when medical treatment, usually a drug, has the opposite effect to that which would normally be expected.  
| **wikipedia**  

| **Patient Medical Condition**  
| This is the information that is recorded and maintained about a patient's diagnosed and/or reported medical condition. This includes such things as diabetes, heart conditions, pregnancy, allergies and intolerances. **Source:** CeRx  
| **CHI**  
| **Master Glossary- March 16, 2009 - R02.04.00-HL7 v3 pan-Canadian Messaging Standards, Canada Health infoway** |

| **Problem**  
| A problem of a given individual can be described by formal diagnosis coding systems (such as DRG's, NANDA Nursing Diagnosis, ICD9, DSM, etc.) or by other professional descriptions of health care issues affecting an individual. Problems can be short or long term in nature, chronic or acute, and have a status. In a longitudinal record, all problems may be of importance in the overall long term care of an individual, and may undergo changes in status repeatedly.  
| **HL7**  
<p>| <a href="http://www.hl7.org/documentcenter/public_temp_CB795262-1C23-BA17-0CB0EE75414D3DBA/calendarofevents/FirstTime/Glossary%20of%20terms.pdf">http://www.hl7.org/documentcenter/public_temp_CB795262-1C23-BA17-0CB0EE75414D3DBA/calendarofevents/FirstTime/Glossary%20of%20terms.pdf</a> |</p>
<table>
<thead>
<tr>
<th><strong>Problem List</strong></th>
<th>A list of current health conditions that are under active management. The list may exclude past problems that are inactive or resolved and include problems of a socio-economic or psycho-social nature that are not diagnoses (such as homelessness, unstable family). Source: iEHR</th>
<th>CHI</th>
<th>Master Glossary- March 16, 2009 - R02.04.00- HL7 v3 pan-Canadian Messaging Standards, Canada Health infoway</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Propensity to</strong></td>
<td>future risk of</td>
<td>UK NHS</td>
<td>SCG Guidance on the Representation of Allergies and Adverse Reaction Information Using NHS Message Templates, NHS Connecting for Health, NPFIT-FNT-TO-SCG-0001.06 - 30.04.08 / Approved / 1.0, Page 8</td>
</tr>
<tr>
<td><strong>Provisional Diagnosis</strong></td>
<td>One which is tentative and could possibly change with new information. Source: CeRx</td>
<td>CHI</td>
<td>Master Glossary- March 16, 2009 - R02.04.00- HL7 v3 pan-Canadian Messaging Standards, Canada Health infoway</td>
</tr>
<tr>
<td><strong>Reaction</strong></td>
<td>It is important to distinguish between two kinds of allergic reaction / adverse reaction entry in the medical record: • Recording an Allergic Response or Adverse Reaction to an item of medication or a substance • Recording a clinician’s opinion about future risk of (or propensity to) an Allergy or other Adverse Reaction if the patient is exposed to a substance. The allergy propensity template is used to populate the patients’ allergy and adverse reactions list. This is a list of all the substances/drugs/food that a person is at future risk of having an adverse reaction or allergy to. Ideally there should be only one entry per</td>
<td>UK NHS</td>
<td>SCG Guidance on the Representation of Allergies and Adverse Reaction Information Using NHS Message Templates, NHS Connecting for Health, NPFIT-FNT-TO-SCG-0001.06 - 30.04.08 / Approved / 1.0, Page 8</td>
</tr>
<tr>
<td>Drug/Substance/Agent</td>
<td>Risk and Reaction Events</td>
<td></td>
<td></td>
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<tr>
<td>----------------------</td>
<td>--------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>drug/substance/food/causative agent.</td>
<td>Logically, events (such as reaction events and risks) must be kept as separate phrases. For example, this is demonstrated in the NHS Connecting for Health (NHS CFH) SCG Guidance paper <em>Representation of Allergies and Adverse Reaction Information Using NHS Message Templates</em> (ref). A risk could exist without a reaction event, such as when a patient knows that they are allergic to a drug but cannot remember any details of the reaction they had experienced (if they had indeed experienced a reaction). Conversely, a reaction event could be recorded, but without the clinician feeling the need to indicate that there is an accompanying future risk, although this would be out of the current design scope. Also, there can be multiple past reactions to a single risk and, potentially, multiple risks associated with a single event. The risk phrase is a terse summary to alert future prescribers, whereas the recording of a reaction event will take a whole clinical encounter to record, including elements such as history, examination, diagnosis and plan. In all, this evidence suggests the need to separate clinical risk phrases from clinical event phrases.</td>
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</tr>
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</table>

<table>
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<tr>
<th>Risk of adversely reacting</th>
<th>an adverse drug reaction can be expressed in terms of an actual reaction event or in terms of a future risk to the patient. As will be shown later in the document, this is an important distinction, given that a patient can experience a reaction (event) without the clinician believing that the drug represents a serious future risk; or, conversely, the clinician may wish to record that the patient is at risk of adversely reacting to a given medication, even if the details of any past reaction are not known. For example, the patient may tell the clinician that they are allergic to penicillin, but are not able to recall any specific reaction event to justify this risk. The clinician may therefore wish to record this as a risk and not an event. Obviously, the confusion of 'risk' and 'event' at this point could be dangerous as future readers of the risk information could place undue confidence in the risk if they think that the clinician has witnessed a reaction in the patient.</th>
<th>UK Microsoft Cited in: Design Guidance- Displaying Adverse Drug Reaction Risks- Microsoft- 28 January 2009 - Version 1.0.0.0, page 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>In physiology, a stimulus (pl. stimuli) is a detectable change in the internal or external environment. The ability of an organism or organ to respond to external stimuli is called sensitivity.</td>
<td>wikipedia <a href="http://en.wikipedia.org/wiki/Sensitivity_%28physiology%29">http://en.wikipedia.org/wiki/Sensitivity_%28physiology%29</a></td>
</tr>
<tr>
<td>Sensitivity</td>
<td>Note this concept is used in article that aimed to 'evaluate the allergen sensitivities, allergen exposures, and associated morbidity for participants in the Inner City Asthma Study',</td>
<td>Inner City Asthma Study: relationships among sensitivity, allergen exposure, and asthma morbidity. Gruchalla RS et al, J Allergy Clin Immunol. 2005 Mar;115(3):478-85.</td>
</tr>
<tr>
<td><strong>Serious Adverse Product Reaction</strong></td>
<td>An adverse product reaction which: · is fatal (results in death) · is life threatening · requires hospitalization or prolongation of a hospitalization · results in persistent or significant disability/incapacity · results in a congenital anomaly/birth defect. Medical and scientific judgment should be exercised in deciding whether expedited reporting is appropriate in other situations, such as important medical events that may not be immediately life-threatening or result in hospitalization but may jeopardize the patient or may require intervention to prevent one of the other outcomes listed in the definition above. These should also be considered serious.</td>
<td><strong>HL7</strong></td>
</tr>
<tr>
<td><strong>Severity Code</strong></td>
<td>DEFINITION: A coded value specifying the intensity of the event.</td>
<td><strong>CDISC</strong></td>
</tr>
<tr>
<td><strong>Severity Grade</strong></td>
<td>Grade refers to the severity of the AE. The CTCAE displays Grades 1 through 5 with unique clinical descriptions of severity for each AE based on this general guideline: · 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</td>
<td><strong>NCI/NIH USA</strong></td>
</tr>
</tbody>
</table>
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. Not all Grades are appropriate for all AEs. Therefore, some AEs are listed with fewer than five options for Grade selection.

Grade 5 (Death) is not appropriate for some AEs and therefore is not an option.

Activities of Daily Living (ADL):

*Instrumental ADL refer to preparing meals, shopping for groceries or clothes, using the telephone, managing money, etc.

**Self care ADL refer to bathing, dressing and undressing, feeding self, using the toilet, taking medications, and not bedridden.

<table>
<thead>
<tr>
<th>Severity Level</th>
<th>An indication of the seriousness of a patient's medical condition or issues. Conditions for which severity levels are assigned include: disease state, allergies, intolerance and contraindications involving combinations of drugs and other conditions.</th>
<th>CHI</th>
<th>Infoway Master Terminology Worksheet (MTW)</th>
</tr>
</thead>
</table>

<p>| Side Effects | Problems that occur when treatment affects healthy cells. Common side effects of cancer treatment are fatigue, nausea, vomiting, decreased blood cell counts, hair loss, and mouth sores. Source: CeRx | CHI | Master Glossary- March 16, 2009 - R02.04.00-HL7 v3 pan-Canadian Messaging Standards, Canada Health infoway |</p>
<table>
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<tr>
<th>Storyboard</th>
<th><a href="http://www.hl7.org/documentcenter/public_temp_CB795262-1C23-BA17-0CB0EE75414D3DBA/calendarofevents/FirstTime/Glossary%20of%20terms.pdf">http://www.hl7.org/documentcenter/public_temp_CB795262-1C23-BA17-0CB0EE75414D3DBA/calendarofevents/FirstTime/Glossary%20of%20terms.pdf</a></th>
</tr>
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<tr>
<td>A narrative of relevant events defined using interaction diagrams or use cases. The storyboard provides one set of interactions that the modeling committee expects will typically occur in the domain.</td>
<td>HL7</td>
</tr>
<tr>
<td>Substance Adverse Event</td>
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<tr>
<td>In the instance of a quality measure, a substance adverse event is an unexpected or dangerous reaction to a substance (e.g., food, environmental agent). Serious adverse events are those that are fatal, life-threatening, permanently/significantly disabling, those that require or prolong hospitalization, and those that lead to congenital anomaly or require intervention to prevent permanent impairment or damage. A time/date stamp is required as are notations indicating whether item is patient reported and/or provider verified.</td>
<td>HL7</td>
</tr>
<tr>
<td>Substance Allergy</td>
<td></td>
</tr>
<tr>
<td>Indicate if the patient experienced a drug reaction as documented by anaphylaxis, or rash. OR A substance allergy is an immunologically mediated reaction that exhibits specificity and recurrence on re-exposure to the offending substance. A time/date stamp is required as are notations indicating whether the item is patient reported and/or provider verified.</td>
<td>HL7</td>
</tr>
<tr>
<td>Tentative Diagnosis</td>
<td></td>
</tr>
<tr>
<td>See definition for Provisional Diagnosis. A provisional diagnosis. A prescriber may prescribe a medication to a patient while awaiting further confirmation about the diagnosis. The provisional diagnosis is a working hypothesis about the patientís condition. Source: CeRx</td>
<td>CHI</td>
</tr>
<tr>
<td></td>
<td>Master Glossary- March 16, 2009 - R02.04.00-HL7 v3 pan-Canadian Messaging Standards, Canada Health infoway</td>
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</table>
Trigger Event

The event that initiates an exchange of messages is called a trigger event. The HL7 Standard is written from the assumption that an event in the real world of health care creates the need for data to flow among systems. The real-world event is called the trigger event. For example, the trigger event “a patient is admitted” may cause the need for data about that patient to be sent to a number of other systems. There is a one-to-many relationship between message types and trigger event codes. The same trigger event code may not be associated with more than one message type.

HL7

http://www.hl7.org/documentcenter/public_temp_CB795262-1C23-BA17-0CB0EE75414D3DBA/calendarofevents/FirstTime/Glossary%20of%20terms.pdf
### Acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Meaning</th>
<th>Note</th>
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<tbody>
<tr>
<td>CPOE</td>
<td>Computerized Provider Order Entry (System)</td>
<td></td>
</tr>
<tr>
<td>EHR</td>
<td>Electronic Health Record</td>
<td></td>
</tr>
<tr>
<td>EMR</td>
<td>Electronic Medical Record</td>
<td></td>
</tr>
<tr>
<td>LIC</td>
<td>Licensed Healthcare Provider</td>
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</tr>
<tr>
<td>PHR</td>
<td>Personal Health Record</td>
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</tr>
<tr>
<td>RD</td>
<td>Registered Dietitian (or Healthcare Provider (PROV-RD))</td>
<td>See Actor/Roles definition for clarification.</td>
</tr>
</tbody>
</table>

### References

#### Medication Allergies and Intolerances

American Academy of Allergy, Asthma and Immunology
Medication and Drug Allergy Reactions:

#### Food Allergies and Intolerances:

Cianferoni, A, Spergel, J. Food Allergy: Review, Classification and Diagnosis
Allergology International. 2009;58:457-466

National Institute of Allergy and Infectious Disease, National Institutes of Health
2012 Food Allergy Resources:
http://www.niaid.nih.gov/topics/foodallergy/Pages/default.aspx

Sampson, H, Maloney, J. “Food Allergies”

http://anhi.org/learning/pdfs/bcdecker/Food_Allergies.pdf

#### Other:

See additional references in the Glossary