



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

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Revision History

NOTE: Project ID 881

Version	Date	Name	Comment
1.0	10/24/12	Elaine Ayres	DRAFT
1.1	11/3/12	Elaine Ayres	Added an introduction, glossary, acronyms, references and HL7 actor standard names.
1.2	11/17/12	Elaine Ayres	Standardized use case format and ensured internal consistency of use cases
1.3	3/13/13	Elaine Ayres	Updates to use cases and glossary based on January 2013 ballot comments. Removal of "Preferences " use case. Addition of "Reconciliation of Lists " use case.
1.4	3/17/13	Lorraine Constable/Jean Duteau	Incorporated model documents
1.5	6/2013	Jean Duteau and Elaine Ayres	DAM finalized based on May 2013 ballot comments in preparation for publication.
1.6	9/2/13	Elaine Ayres	May ballot was "comment only" based on clerical error. Ballot ready for publication awaiting completion of "informative ballot" cycle. Minor updates made to document to reflect dates, and work group chairs.
1.7	1/19/14	Elaine Ayres, Jean Duteau, Lorraine Constable	Editorial changes based on September 2013 OOC ballot comments. Added use case on "added in error", added criticality matrix

Foreword

Publication of this Technical Report that has been registered with ANSI has been approved by the accredited standards developer Health Level Seven International (HL7), 3300 Washtenaw Ave., Suite 227, Ann Arbor MI 48104, USA. This document is registered as a Technical Report according to the procedures for the Registration of Technical Reports with ANSI. This document is not an American National Standard and the material contained herein is not normative in nature. Comments on the content of this document should be sent to the HL7 Clinical Interoperability Council Work Group, 3300 Washtenaw Ave., Suite 227, Ann Arbor MI 48104-4261 or hq@hl7.org. This document was registered as a Technical Report to help 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 several 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 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 and intolerance 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), and how to address an allergy entered in error.
- To demonstrate the reconciliation of two different allergy and intolerance lists.

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 several 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 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 and intolerance 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).
- To demonstrate the reconciliation of two different allergy and intolerance lists.

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 and intolerances.

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. Allergy and intolerance clinical models now serve as the technical companion document to this domain analysis model.

Use Cases

The diagram below summarizes the use cases included in the scope of this model. (Note, all diagrams are excerpted from the Enterprise Architect Model that accompanies this document)

Many of the use cases all have similar steps. Those steps are abstracted into one generic use case named Record Adverse Sensitivity. This use case does not have a corresponding textual description since it is shared by the other use cases as indicated in the diagram. The Record Adverse Sensitivity use case is represented by one activity diagram which covers the common steps of the specialized use cases.

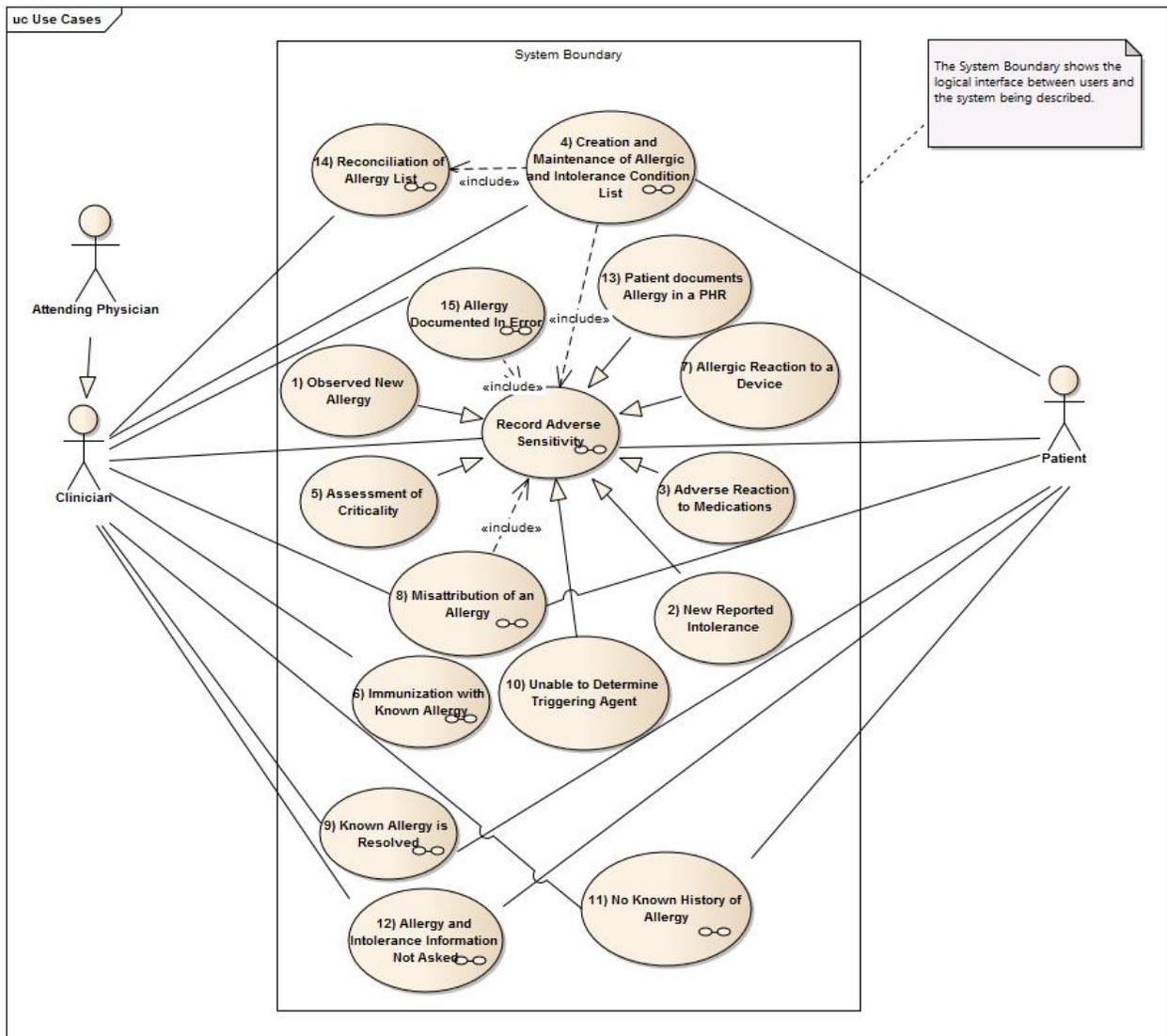


Figure 1 - Allergy/Intolerance Use Case Diagram

These use cases are further elaborated in subsequent sections.

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 Department (ED) *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 for a newly diagnosed allergy observed by a health care provider 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.
2. Ned eats peanut butter sandwich.
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 Banaid, 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 ED, Ned's symptoms have diminished but the *ED physician is able to observe evidence of the adverse reaction*.
7. Ned is further treated in the ED.
8. The ED physician takes a history from Ned and his mother.
9. Based on the clinical history and the observation of symptoms the ED physician determines there is a relationship between the peanut butter sandwich and the subsequent adverse reaction.
10. The ED 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

ED Provider: Eric Emergency

Allergist: Ramsey Reaction

Registered Nurse: Nancy Nightingale
School Nurse: Barbara Banaid

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 Banaid.

Fred starts telling Nurse Banaid 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 ED. When the ambulance arrives, Barbara Banaid 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 ED. 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 ED 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.

Post Conditions

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 with no previously documented food allergies or intolerances manifest an adverse reaction to lactose (*patient reported*).

Exceptions: none

Use Case Sequence Steps:

1. The patient Eve Everywoman has just completed a course of azithromycin 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 azithromycin treatment.
3. The patient tells her primary care provider that her symptoms seem to be exacerbated by milk and milk products. (NOTE – patient reported reaction).
4. The primary care provider completes his evaluation determining that the patient may have become lactose intolerant do 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 azithromycin, Eve began to feel nauseous and had multiple episodes of diarrhea. After finishing the azithromycin 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 azithromycin, and her symptoms seem to be worse after meals, particularly when she drinks milk or eats milk-related products such as soft cheese. (*Patient reported intolerance*)

Medications – completed three day course of azithromycin. 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.

Post Conditions

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 a clinician observed adverse reaction to medications in an EHR-S.

Assumptions

Hospital has EHR-S 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 does not have an existing EHR-S record at hospital.

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 (ED) 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 EHR-S for the patient's history/clinical information including allergy/intolerance and adverse reaction data.
4. The 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 EHR-S and takes full medical and medication histories.
6. The ED physician evaluates the patient's condition, makes a diagnosis from the observed condition, and attributes the diagnosed condition to a probable case of hypersensitivity reaction to sulphonylurea (Glicazide) order and gives appropriate treatment.
7. ED physician documents in EHR-S patient's clinical details including presenting problem, medical history, medication history, treatment and outcomes.
8. ED physician updates allergy/intolerance list on allergy/hypersensitivity to recently prescribed medication (Glicazide)
9. ED physician generates a discharge summary using the hospital clinical information system or EHR-S for transmission to patient nominated primary care physician Patricia Primary. The discharge summary contains the allergy/intolerance list which includes an entry of Glicazide
10. ED physician enters adverse reactions details in EHR-S allergy/intolerance list and 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 - None

Notes

Allergy/intolerance details captured and exchanged include:

medication class, medication name, dose, date and time of medication start, date and time of adverse reaction onset, adverse reaction details, notation of clinical provider observation of reaction manifestation, date and time of presentation to hospital/ED, date and time of treatment and details, date and time of resolution, updated allergy/Intolerance list, informant/information provider (patient), author (may also be the attending physician)

Actors

ED attending physician - Eric Emergency

Patient - Adam Everyman

*Primary care physician/GP - Patricia Primary
Community Pharmacist - Susan Script*

Use Case Scenario

A 60-year old man Adam Everyman presents himself at the Emergency Department (ED) 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 EHR-S does not have pre-existing allergy/intolerance information on patient

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). (*Provider observed reaction*)

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.

References:

1. http://books.google.com.au/books?id=-WOn3SqdkxgC&pg=PA122&lpg=PA122&dq=Gliclazide+and+erythema+multiforme&source=bl&ots=4KNCFPpv9J&sig=UijQzGwhd7jJ5e-r4fmh-yKhyos&hl=en&sa=X&ei=A6eMT7X5M_GuiQeYqrzHCQ&ved=0CFsQ6AEwBw#v=onepage&q=Gliclazide%20and%20erythema%20multiforme&f=false
2. <http://www.rdehospital.nhs.uk/docs/patients/diabetes/RDE%20diabetes%20-%20type%202%20glycaemia%20-%20sulphonylureas.pdf>

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

Note – see Use Case #14 for Reconciliation of an Allergy/Intolerance List

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.

Condition

A new list of allergy and intolerance conditions is created by a primary care provider. Additional documented conditions from other providers inform the creation of the list and subsequent updates to the list.

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 (List A) 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) (List B)
2. The previous medical record is reviewed and reconciled with the patient history. PCP #2 creates the initial allergy and intolerance list of conditions (reconciliation of List A and List B)
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 (List B) 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 (List C)
6. A summary of the emergency visit is sent to PCP #2 by the emergency room with erythromycin allergy added to list (List C).
7. PCP #2 reviews the emergency room summary (List C) and discusses the reaction history with the patient. PCP #2 then reconciles list of allergies and intolerances and updates the list (List B)

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 Department (ED) 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 (List A). 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 on a new electronic allergy and intolerance list (List B).

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 (List B)

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 (List B) from the local Health Information Exchange as a CCD and Eric Emergency has added an allergy to erythromycin (List C).

The primary care provider (PCP #2) reviews Eve's account of the episode and reviews the summary from the emergency department (List C). 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 (List B); the erythromycin allergy is changed to "inactive" and erythromycin intolerance is added to the list. This updated allergy and intolerance list (List B) is then available to other providers, and to the patient's personal health record.

Use Case 5: Assessment of Criticality

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 within an electronic health record and enabling the exchange of this attribute to other systems such as a PHR.

Condition

A child presents with a new adverse reaction to a food substance (*patient care provider observed*) and the clinician-based assessment of the condition.

Assumptions

- Pediatrician Practice has EHR-S 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 - None

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 pediatrician clinic.
3. The pediatrician accesses the clinic EHR-S 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 EHR-S 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 EHR-S 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 documents 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. The allergy/intolerance and adverse reaction and assessed criticality information is also transmitted to the patient's PHR where applicable (e.g. if requested by patient's parents)

Notes

Allergy/intolerance details captured and exchanged include: adverse reaction preceded by

exposure (e.g. physical contact) with a specific substance type, the relationship of the exposure to a substance and the manifestation of the adverse reaction including severity, 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)

Actors

Attending physician (pediatrician) – Karen Kidder

Patient(child) – Kari Kidd

Parents (subject of care and parents as informant) Nelda and Ned Nuclear

Use Case Scenario

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.

By the time of arrival 20 minutes later Kari's hives have disappeared and she says she feels okay. The pediatrician obtains the history of the episode from Kari's parents who assert that Kari 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.

Based on the observed reaction, the pediatrician Kari Kidder 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.

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 noting that future ingestion of peanuts may cause a more severe reaction requiring immediate medical treatment.

The adverse reaction resolved without the need for intervention and with no residual functional impairment or consequences. The patient's medical record is updated with the diagnosis of mild allergic reaction to peanuts 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 peanuts criticality details are transmitted to patient's PHR as requested by patient's parents.

Discussion Of Severity Vs. Criticality

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.
- 5.

Table 1 provides a variety of scenarios related to the documentation of drug treatments and how severity and the criticality attribute based on clinical judgment would be classified.

Reaction History	Reaction Severity	Allergy List Entry	Criticality	Treatment Indication	Decision
Hives and swelling after PCN shot for strep throat as teenager	Moderate	Penicillin allergy	High	23 yo with abnormal aortic valve needs penicillin prophylaxis for dental procedure	Substitute erythromycin
Hives and swelling after PCN shot for strep throat as teenager	Moderate	Penicillin allergy	High	Pregnant 23 yo with + serology and tertiary syphilis needs high dose parenteral penicillin	Penicillin desensitization protocol in ICU
Red eyes, sore mouth after 2 doses trimethprim-sulfamethox	Mild	Bactrim allergy	High	25 yo with pneumocystis pneumonia	Treat with dapsone and trimethoprim

Reaction History	Reaction Severity	Allergy List Entry	Criticality	Treatment Indication	Decision
Severe nausea during numerous courses of trimethoprim-sulfamethox	Mild	Bactrim allergy	Low	25 yo with pneumocystis pneumonia	Treat with trimethoprim - sulfamethoxazole and anti-nausea medication
Severe anxiety, dysphoria, and palpitations after epinephrine SQ for respiratory distress	Mild	Epinephrine intolerance	Low	Urgent presentation with moderate respiratory distress, diffuse wheezing during URI	Treat with albuterol aerosol
Severe anxiety, dysphoria, and palpitations after epinephrine SQ for respiratory distress	Mild	Epinephrine intolerance	Low	Urgent presentation with moderate respiratory distress, diffuse wheezing, hives, periorbital edema	Treat with SQ epinephrine
Measles-like rash while on amoxicillin for "bronchitis" as toddler	Mild	Amoxicillin allergy	Low	14 yo with skin abscess due to staphylococcus sensitive only to tetracycline and dicloxacillin	Treat with oral dicloxacillin
Hives and facial swelling while on amoxicillin for "bronchitis" as toddler, required ED visit	Moderate	Amoxicillin allergy	High	14 yo with skin abscess due to staphylococcus sensitive only to tetracycline and dicloxacillin	Treat with oral tetracycline

Table 1 – Criticality attribute examples.

For Additional Information On Severity Vs. Criticality See Appendix A.

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. 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.
9. The allergy to egg remains on the allergy and intolerance list.

Post Conditions

- The patient summary record is updated to reflect the provision of the vaccine despite the known allergy.
- Physician writes a consult note for the patient pediatrician, adds a note to the patient summary record, and signs the International Certificate of Vaccination.

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. Based on medical history, the child has a documented allergic reaction to eggs. In order to travel to Africa with her parents she must receive the YF-VAX®, a yellow fever vaccine prepared from a virus grown in chick embryos and are the most likely to cause allergic reaction in egg- or chicken-allergic individuals. (CIG, p. 85).

The physician determines that the vaccination for yellow fever is more important. Therefore vaccination should be conducted but under close medical supervision. The physician administers the vaccine.

Patient has received the vaccine and was released without significant adverse reaction. The patient allergy and intolerance list is updated indicating the evaluation of the allergic conditions and decision to administer the yellow fever vaccine under medical supervision. The allergy to egg remains on the allergy and intolerance list.

References

- CIG- Canadian Immunization Guide, seventh edition, Public Health Agency of Canada, 2006: <http://www.phac-aspc.gc.ca/publicat/cig-gci/index-eng.php>
- Yellow fever- Fact sheet N°100 - January 2011, WHO (<http://www.who.int/mediacentre/factsheets/fs100/en/index.html>) and (<http://www.who.int/vaccines/en/yellowfever.shtml>)
- (Yellow Fever Vaccine Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2002-
<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. 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.

Condition

A patient has a clinician observed adverse reaction to an implanted device.

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 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 labels (*Clinician observed reaction*). 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/Intolerance

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

Following the implant of a nickel-based knee implant, an adverse reaction to nickel is suspected. Further testing reveals no allergy to nickel and the nickel allergy is changed from active to inactive on the allergy and intolerance list.

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 added 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 "*refuted*", 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 Conditions

None

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 Multicompartmental 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 visits the pediatrician Karen Kidder for her annual physical exam. The pediatrician notes the milk allergy.
2. Mother notes some ingestion of milk products in baked goods without reaction.
3. The pediatrician recommends a food challenge.
4. A food challenge without any reaction demonstrates that Kari is no longer manifesting a reaction to milk.
5. Milk allergy is updated 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. 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 and intolerance list to show that the milk allergy is now "resolved". Kari is now able to consume milk and milk products without reaction.

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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/EHR-S; 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.

Condition

A patient receives a multi-ingredient medication resulting in an adverse reaction (*clinician observed*). Because of the multiple drug ingredients it is not possible to determine the triggering agent.

Assumptions

Hospital has EHR-S 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 reaction details to be sent to nominated community pharmacist
- Updates PHR with recent adverse reaction details

Pre-conditions - None

Exclusions - None

Use Case Sequence

1. Patient was administered a dose of multi-ingredient antibiotic to treat a urinary tract 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 EHR-S 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 an adverse reaction to the multi-ingredient medication in question.
8. Attending physician prescribed appropriate intervention(s) including treating signs and symptoms of adverse reaction, cancellation of the prescription for the multi-ingredient medication in question.
9. Attending physician documented presenting problem, 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 EHR-S 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. 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 EHR-S allergy/intolerance and adverse reaction 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 - None

Notes

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

Actors

Attending physician - Harold Hippocrates

Patient– Eve Everywoman

Attending physician - Aaron Attend
Primary care physician – Patricia Primary
Community pharmacist– Susan Script

Use Case Scenario

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 and vomiting) and allergic skin reactions (such as rash /urticaria and itching), and wheezing as observed by the attending physician.

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.

The adverse reaction signs and symptoms resolve gradually after withdrawal of the 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*”.

A discharge summary sent to Patricia Primary includes an 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 no known history of allergy or intolerance and adverse reaction to a medication or substance. The information is then captured in the EHR-S; and to support the generation and exchange of such information in a hospital discharge summary.

Condition

Following a clinician interview of a patient it is determined that there are no known allergies or intolerances.

Exclusions

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

Preconditions

- The hospital uses EHR-S supporting the documentation of the adverse reaction event, management and revision of allergy/intolerance list
- EHR-S capable of generating and transmitting electronic discharge summary

Use Case Sequence of Steps

1. The patient presents to the ED 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 EHR-S was completed.
6. The attending physician notes in the allergy/intolerance list at the time of admission that based on the information provided by the patient there are no known allergies or intolerances.
7. Discharge summary generated using hospital clinical information system or EHR-S

Post Conditions

Updated EHR-S 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 headache and with painful skin abrasions.

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.

Treatment was provided for injuries. The allergy/intolerance list of conditions was updated with entry of “*no known allergy/intolerance to medication or substance*”. The Hospital EHR-S on this patient is updated with “no known allergy/intolerance to medication or substance” information.

Post Conditions

- 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 an EHR-S; and to support the generation and exchange of such information in a hospital discharge summary.

Condition

A patient receiving care is unable to provide a history of allergies or intolerances.

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

- The hospital uses EHR-S supporting the documentation of the adverse reaction event, management and revision of allergy/intolerance list
- EHR-S capable of generating and transmitting electronic discharge summary

Use Case Sequence of Steps

1. The patient presents to the Emergency Department (ED) with no ability to respond to questions and no existing EHR-S.
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 of allergy/intolerance list in EHR-S.
5. EHR-S record with “allergy/intolerance history not asked – cognitively impaired patient” (or “allergy/intolerance history cannot be obtained”) entry to allergy/intolerance list.
6. Patient was transferred to State hospice service for ongoing care.
7. Discharge summary generated using EHR-S.

Post Conditions

- Updated 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 center 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 (ED) of a local hospital by an ambulance. Patient was not known to the hospital. A welfare card in patient’s shirt pocket allowed identification of the patient to be established but was inadequate for tracing of his medical or health care provider. No previous medical history on this patient from any other source could be identified by the hospital.

A medical history could not be obtained. A history of allergy or intolerance not asked as patient is cognitively impaired. Based on tests the patient was diagnosed with alcoholic cirrhosis of liver. His contusions were treated but the patient does not recover cognitive function adequate to provide a full medical history. The patient is discharged to State hospice services for ongoing care.

The hospital EHR-S allergy/intolerance list for this patient entry is “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-S 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-S.
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.

Actors

Patient – Adam Everyman

Primary Care Provider – Patricia Primary

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 Patricia Primary. 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.

NOTE: Use case on Preferences removed. This use case can now be found in the Nutrition Diet Orders Domain Analysis Model.

Use Case 14: Reconciliation of Allergy/Intolerance List

(New Use Case 3/2013)

Description

The purpose of this use case is to describe the reconciliation of Allergy/Intolerance lists or details obtained from different source(s) by a health care provider. The provider compares the contents of the lists or details to identify discrepancies and errors. Any discrepancies or errors are verified with the sources and the patient/parent(s)/guardian(s). The allergy/intolerance contents in the provider's EHR-S repository will be updated based on the result of the verifications. A reconciled Allergy/Intolerance list may be sent to other relevant sources (e.g. the sources that provided the pre-reconciled allergy/intolerance lists, the Pharmacist and PHR or shared EHR-S nominated by the patient).

Condition

Allergy and intolerance lists compiled by different clinical care providers are merged and edited for discrepancies.

Exceptions

None

Preconditions

1. The EHR-S of the provider contains allergy/intolerance details about the patient under his/her care
2. The provider receives or obtains allergy/intolerance details/list from different sources
3. The patient has documented allergies

Use Case Steps

1. Adam Everyman is discharged from hospital after a week in the respiratory unit because of exacerbation of his chronic obstructive pulmonary disease (COPD). His pulmonologist Dr Penny Puffer sends his primary care physician (PCP) Dr. Patricia Primary a discharge summary that contains the hospital allergy/intolerance list.

2. Three days after discharge, Adam attends a follow-up appointment with his PCP, Dr Patricia Primary.
3. At the follow-up consultation, Dr Primary reviews the discharge summary from the hospital and discovers that there are discrepancies between the allergy/intolerance list in the discharge summary and the patient's allergy/intolerance list detailed in the health care system EHR-S repository
4. Dr Primary reviews the discrepancies with Adam and reconciles the inconsistencies. Dr Primary updates the patient's allergy and intolerance list in the health care system EHR-S repository with new allergy/intolerance details based on information from the patient and the hospital discharge summary.
5. With the consent of the patient, Dr Primary generates a reconciled allergy/intolerance list and sends the list to Dr Patricia Puffer, the patient's community pharmacist Dr Susan Script and Adam Everyman's Personal Health Record (PHR)

Post Conditions

None

Actors

Patient: Adam Everyman

Treating Pulmonologist (hospital): Dr Patricia Puffer

PCP: Dr Patricia Primary

Pharmacist: Ms Susan Script

Use Case Scenario

Adam Everyman, a 48-year old patient, is under the care of his PCP, Dr Patricia Primary. He has a medical history of chronic obstructive pulmonary disease (COPD), gastro-esophageal reflux disorder (GORD) and Type II diabetes Mellitus (diagnosed 6 months ago). His EHR-S held at the Dr Primary's clinic shows that he has allergy to peanuts (reactions include: hives, tightening of the throat, wheezing); allergy/intolerance to amoxicillin + clavulanic acid (reactions include: nausea, vomiting, diarrhea, rash); lactose intolerance (reactions: flatulence and diarrhea).

Hospital Care: Adam was admitted to the hospital over the long weekend holiday due to acute exacerbation of his COPD and is managed in the respiratory unit of the hospital by Dr Patricia Puffer. It was confirmed that the exacerbation was triggered by an influenza infection and was treated with a course of antibiotic – clarithromycin. During the in-hospital care, medications were prescribed by Dr Puffer for treatment of the patient's other conditions including diabetes. On Day 3 of the hospitalization, the patient started to exhibit signs and symptoms including: headache, dizziness, skin rash, and hypoglycemia. By process of elimination, it was determined that the adverse reactions were related to Glicazide. This oral hypoglycemic agent was prescribed by the Dr Patricia Primary (PCP) four weeks prior to current episode of hospital admission. The medication was stopped and the patient recovered with no permanent adverse effect.

Discharge: After a week of in-hospital management, the patient's condition improved significantly and was considered fit for discharge. A discharge summary was prepared and sent electronically to the patient's PCP. A follow-up appointment was arranged by the hospital for the patient to be seen by his PCP 3 days after discharge.

PCP follow-up: At the follow-up consultation, Dr Primary discovered the following discrepancies in the discharge summary allergy/intolerance list after comparing to the patient's allergy/intolerance list in the health care system EHR-S repository:

- Allergy/intolerance to amoxicillin + clavulanic acid was not recorded at the hospital
- New entry of allergy/intolerance to Glicazide based on Adam's discharge summary.

Dr Primary verified with Adam that he (the patient) did not mention amoxicillin + clavulanic allergy / intolerance history to Dr Puffer in the hospital; and that he did experience an adverse reaction to Glicazide.

Dr Primary updated the health care system EHR-S repository allergy/intolerance list with details on Glicazide (including signs and symptoms), ceased the prescription on Glicazide and reviewed diabetic treatment for the patient. Dr Primary generated a reconciled allergy/intolerance list and sent it electronically to the hospital, the patient's pharmacist and the patient's PHR

Use Case 15: Allergy or Intolerance Added to List in Error

Description

The purpose of this use case is to describe a scenario where the healthcare professional documents an allergy or intolerance in error within an electronic health record. The incorrect documentation is subsequently removed from the allergy and intolerance list. Clinicians would no longer see this entry, but the entry remains in the database and is available via the audit trail. The removal would include the reason.

Conditions

The healthcare organization uses an electronic health record.

Exceptions

None

Preconditions

None

Use Case Sequence Steps

1. Adam Everyman is a healthy male, age 24 who is admitted to the emergency department following a car accident. Adam has a fractured femur and multiple contusions. His remaining medical history is unremarkable. Adam reports no known allergies or intolerances.
2. Eric Emergency begins to document Adam's history in the electronic health record but does not complete the entry of "no known allergies". Eric is then called away to see an incoming patient Ned Nuclear who has arrived in anaphylactic shock following an exposure to peanuts. When Eric returns to the emergency department computer workstation, his session has expired. Upon logging in, he selects Adam Everyman's medical record and documents an allergy to peanuts in Adam's allergy and intolerance list.

3. After saving Adam Everyman's file and moving on to complete the documentation for Ned Nuclear, Eric Emergency realizes he has entered the peanut allergy into the wrong chart.
4. Eric Emergency adds the peanut allergy to Ned Nuclear's allergy list and then returns to Adam Everyman's chart to correct the error. The peanut allergy on Adam Everyman's allergy and intolerance list is marked as an erroneous entry with reason (data entry error) and the entry for peanut allergy is removed from Adam's allergy and intolerance list. The allergy list is then updated with the correct information "no known allergies or intolerances".
5. Ned Nuclear's allergy and intolerance list correctly displays an allergy to peanuts.
6. Adam Everyman returns home and logs into his personal health record. Upon reviewing his history from his emergency room visit, he notes that his allergy and intolerance list includes "no known allergies or intolerances".

Actors

Patient #1 – Adam Everyman

Patient #2 – Ned Nuclear

Emergency Department (ED) Physician – Eric Emergency

Use Case Scenario

Adam Everyman is a healthy male, age 24 who is admitted to the emergency department following a car accident. Adam has a fractured femur and multiple contusions. After an examination by Eric Emergency, the ED physician finds that the remaining medical history is unremarkable. Adam reports no known allergies or intolerances. Eric Emergency begins to document Adam's history in the electronic health record but does not complete the entry of "no known allergies". Eric Emergency is called away to see an incoming patient Ned Nuclear who has arrived in anaphylactic shock following an exposure to peanuts.

When Eric Emergency returns to the emergency department computer workstation 15 minutes later, his session has expired. Upon logging in, Eric selects Adam Everyman's medical record and documents an allergy to peanuts in Adam's allergy and intolerance list. After saving Adam Everyman's file and moving on to complete the documentation for Ned Nuclear, Eric Emergency realizes he has entered the peanut allergy into the wrong chart. Eric Emergency adds the peanut allergy to Ned Nuclear's allergy list and then returns to Adam Everyman's chart to correct the error.

The peanut allergy on Adam Everyman's allergy and intolerance list is marked as an erroneous entry with reason (data entry error) and the entry for peanut allergy is removed from Adam's allergy and intolerance list. The allergy list is then updated with the correct information "no known allergies or intolerances". Ned Nuclear's allergy and intolerance list correctly displays an allergy to peanuts.

Adam Everyman returns home and logs into his personal health record. Upon reviewing his history from his emergency room visit, he notes that his allergy and intolerance list includes "no known allergies or intolerances".

Activity Diagrams

The following activity diagrams incorporate the steps from the use cases and show the information flow that arises as the Patient and Clinician interact. (Note, all diagrams are excerpted from the Enterprise Architect Model that accompanies this document)

Record Adverse Sensitivity

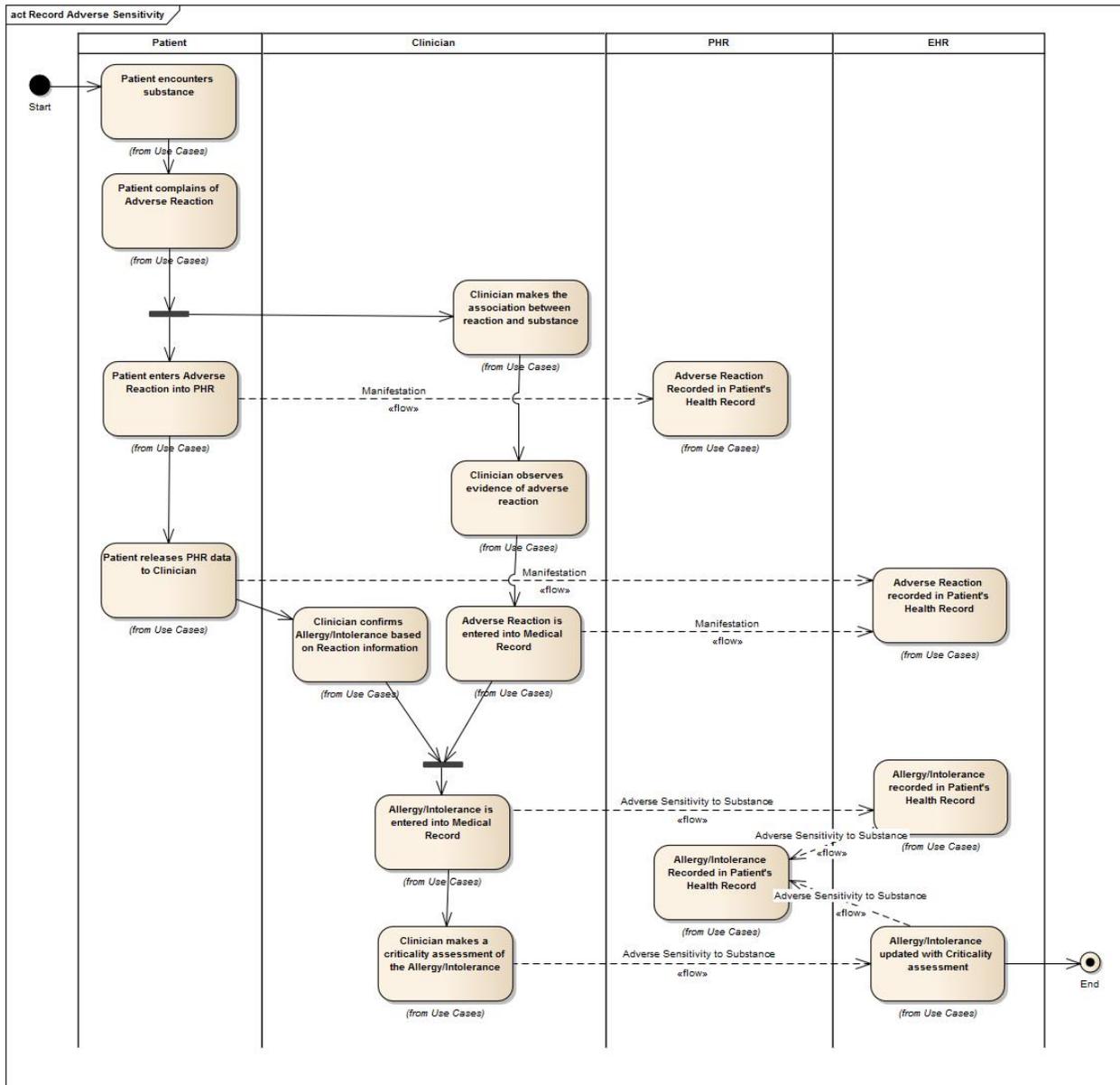


Figure 2 - Record Adverse Sensitivity Activity Diagram

The Record Adverse Sensitivity activity diagram shows two flows that result from a patient experience a reaction to a substance and that result in an allergy/intolerance being entered into the patient's electronic health record (EHR-S). One flow is the case of a patient making a doctor's appointment and describing the reaction to the clinician. This results in the clinician

making data entries into the EHR. The other flow is where the patient has a personal health record (PHR) and enters the reaction information directly into the PHR. There is still an interaction with the clinician but the information flows are different.

This activity diagram is the core diagram of the Allergy/Intolerance model. Many of the use cases inherit the steps of this diagram, either directly or by inclusion, as indicated on the Use Case diagram.

Allergy List Reconciliation

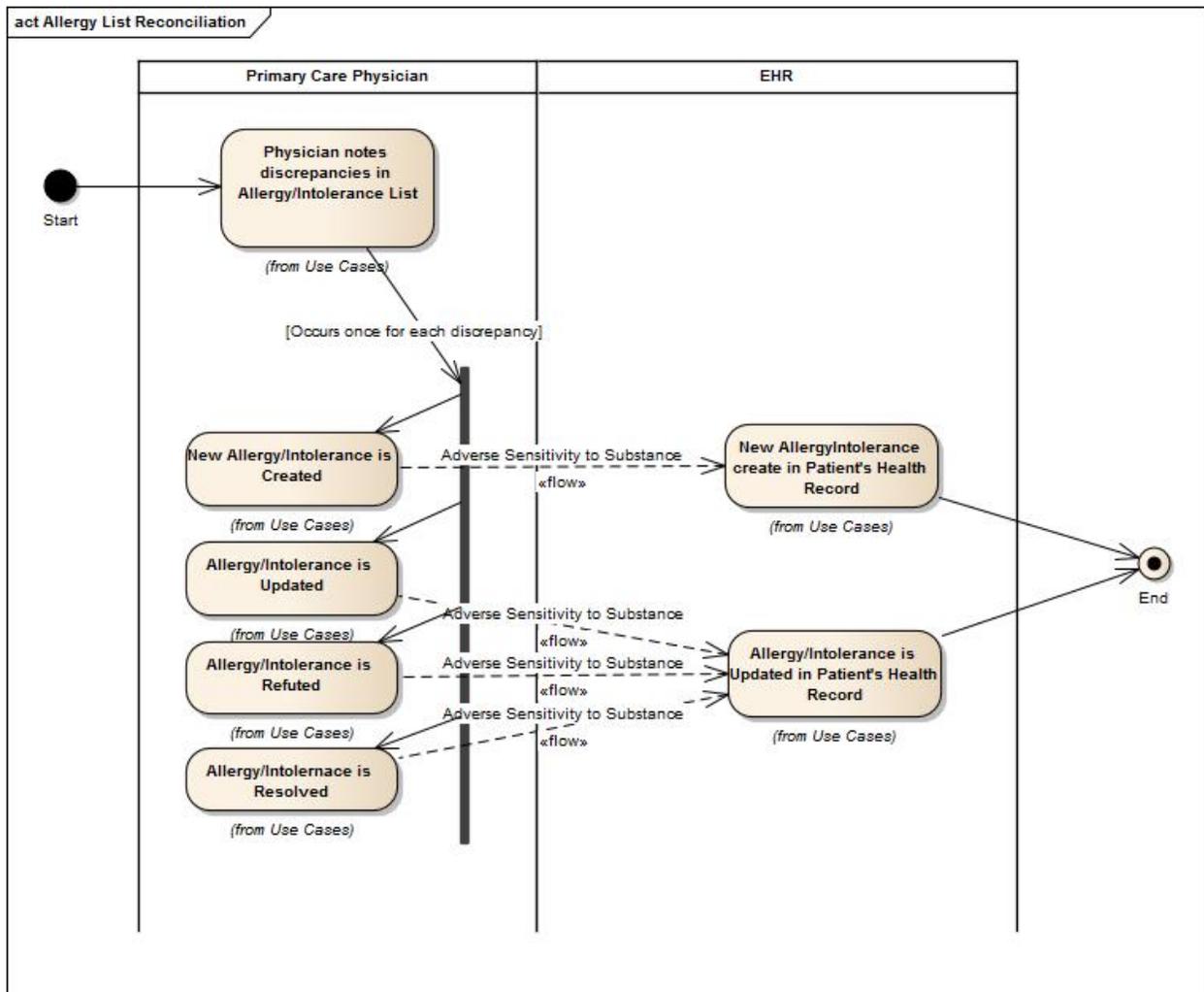


Figure 3 - Allergy List Reconciliation Activity Diagram

Reconciliation of an Allergy List is a central piece of a clinician’s review of a patient’s EHR-S. When reviewing the Allergy List, there are a number of activities that may occur – a new allergy/intolerance may be created, an allergy/intolerance’s details may be updated, or an allergy/intolerance’s state may be refuted or resolved.

Maintain Allergy List

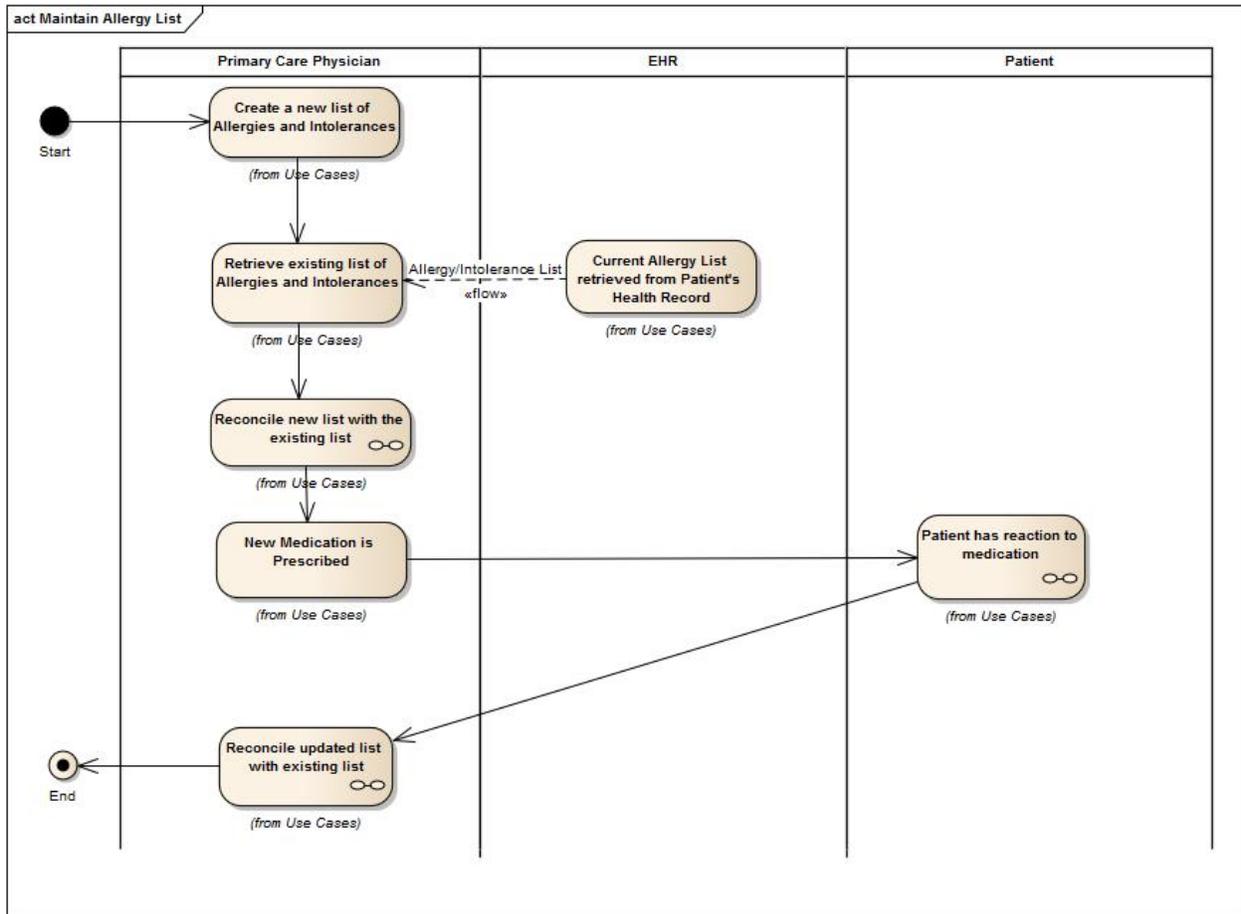


Figure 4 - Maintain Allergy List Activity Diagram

The Maintain Allergy List activity diagram includes two earlier activity diagrams. The Allergy List Reconciliation steps are included in two of the Primary Care Physician's activities while the Record Adverse Sensitivity steps are included when the Patient has a new reaction to a medication.

Misattribution of an Allergy

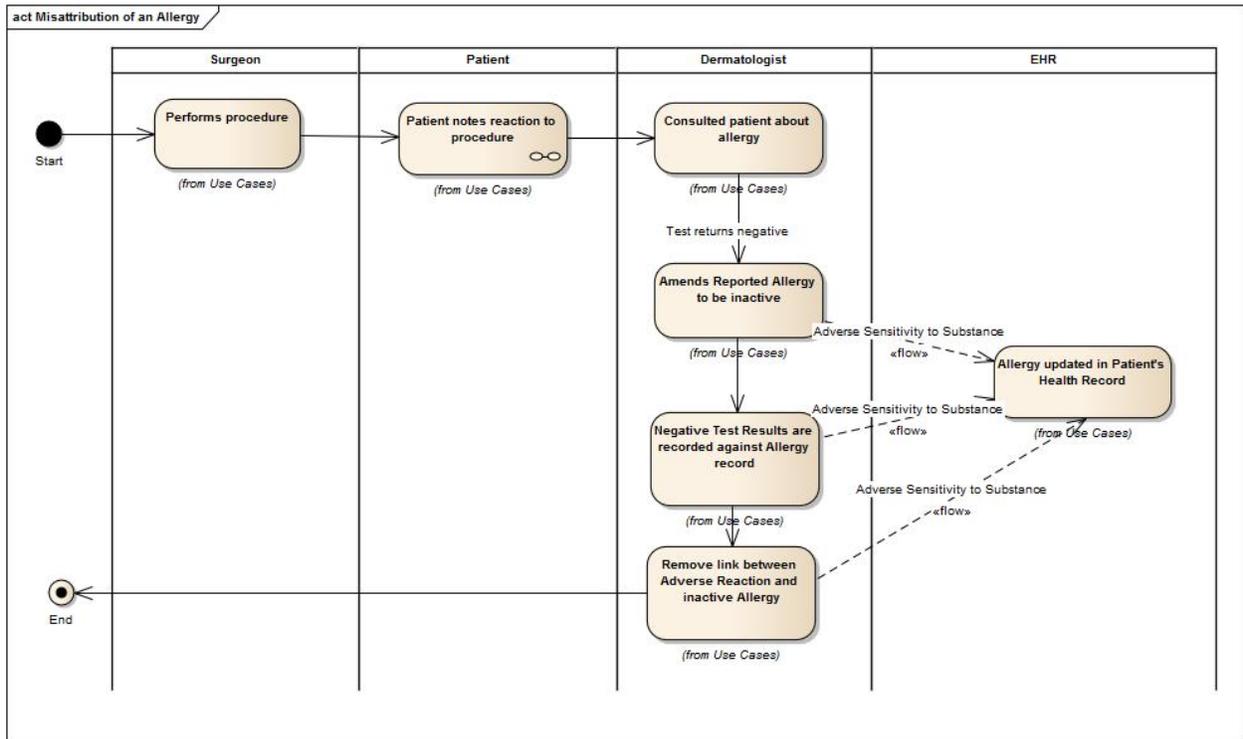


Figure 5 - Misattribution of an Allergy Activity Diagram

The Record Adverse Sensitivity steps are included when the Patient has a reaction to a procedure. All three of the activities that result due to a negative test arise in the allergy being updated in the EHR-S. Although the diagram shows these steps resulting in three updates, it is conceivable that one update would be done after the last step.

Allergy Entered In Error

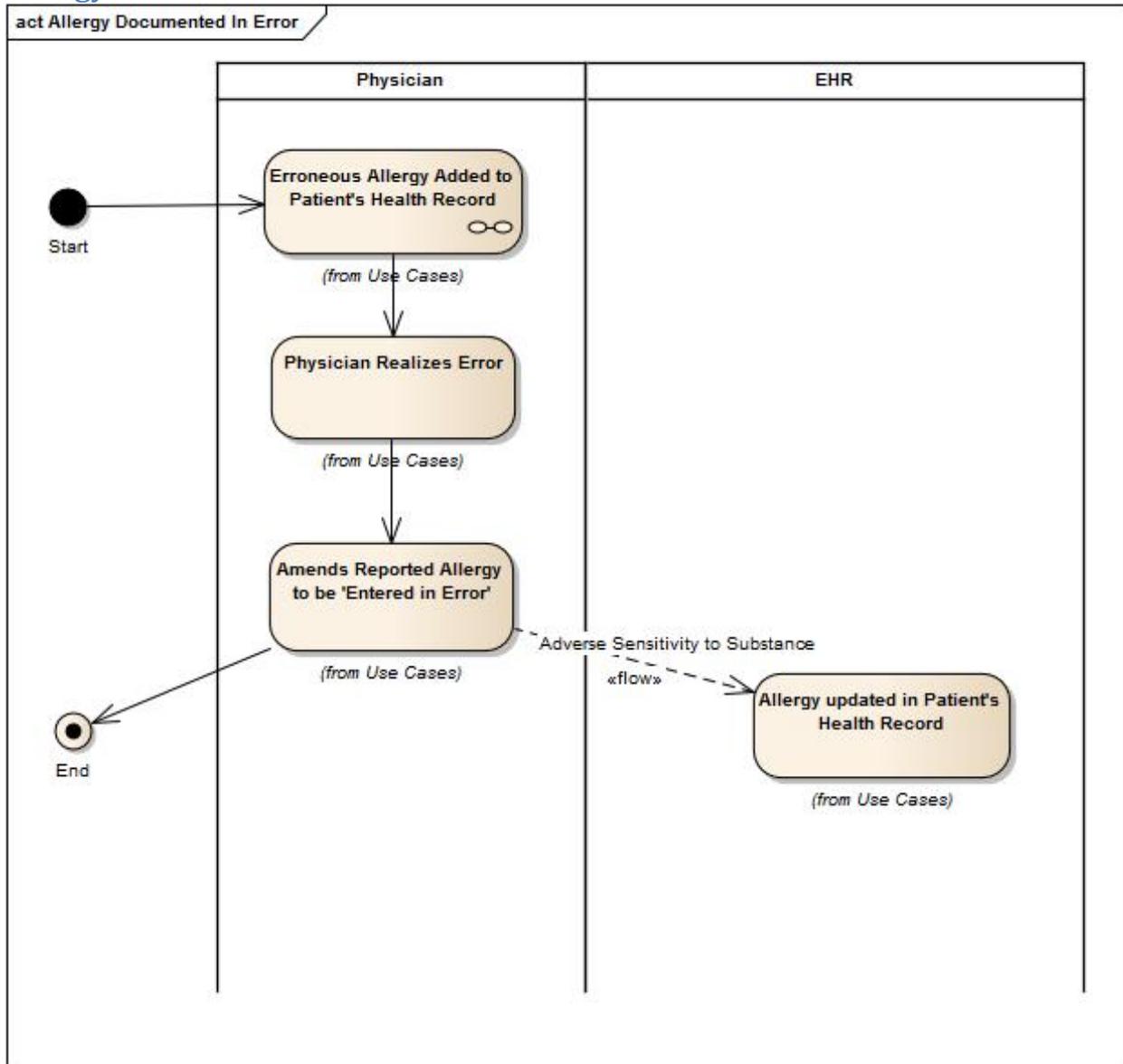


Figure 6 - Allergy Entered In Error Activity Diagram

This diagram shows the steps taken when an adverse sensitivity is discovered to have been entered in error. Although the diagram shows a direct link between when the record was added to the patient's health record and when the entering provider realizes the mistake, this might actually occur over a long period of time.

Manage Allergy Contraindication

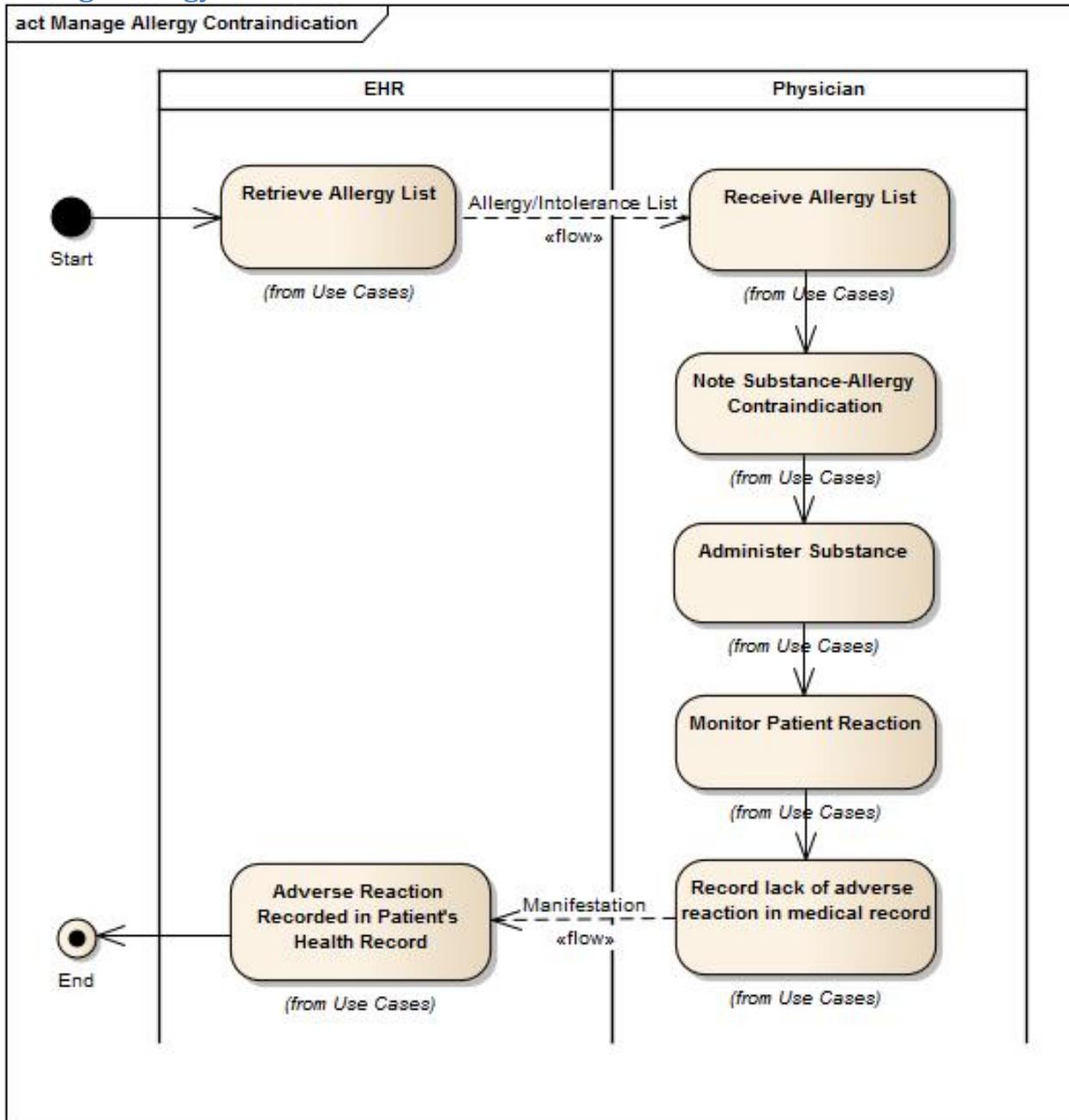


Figure 7 - Manage Allergy Contraindication Activity Diagram

The Manage Allergy Contraindication activity diagram is used by the Immunization with Known Allergy use case.

Known Allergy is Resolved

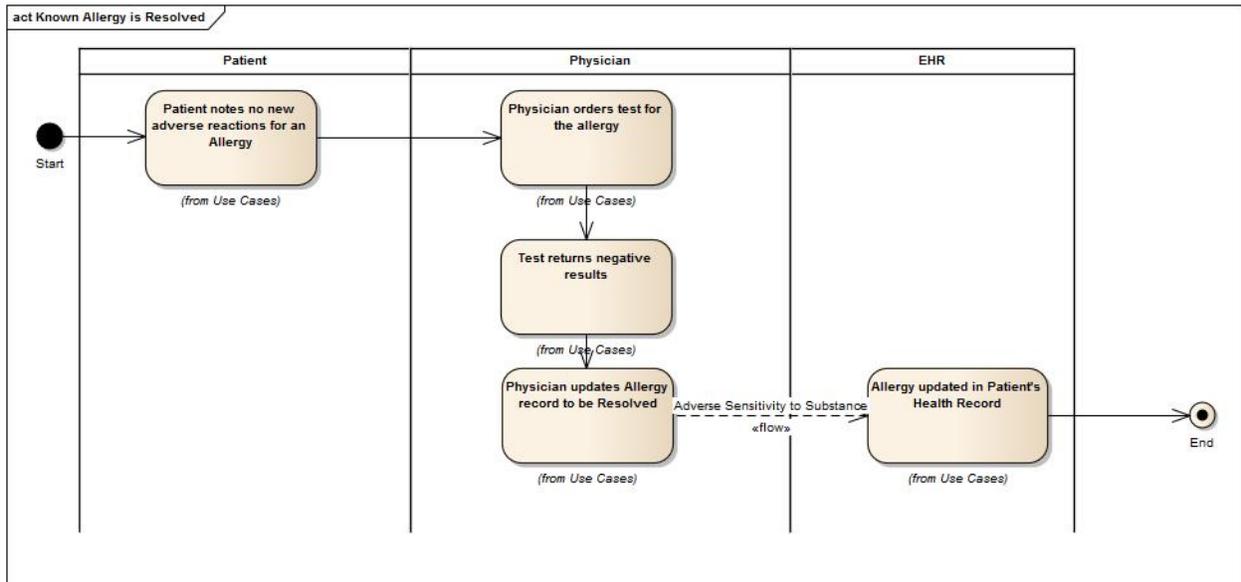


Figure 8 - Known Allergy is Resolved Activity Diagram

This activity diagram is similar to the Misattribution of an Allergy but deals with the case where a previous allergy has appeared to resolve itself, i.e. the patient used to suffer reactions but no longer does.

No Known History of Allergy

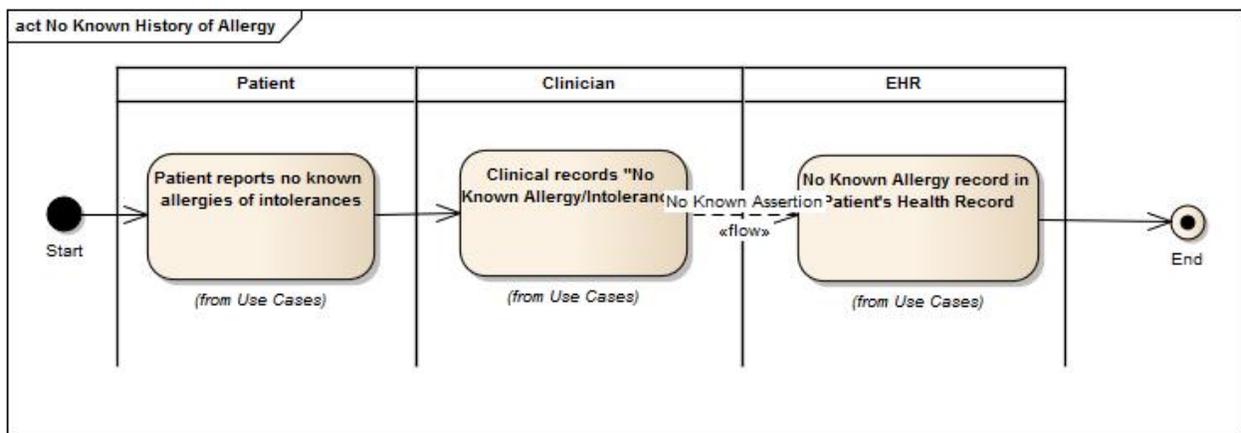


Figure 9 - No Known History of Allergy Activity Diagram

To distinguish between an absence of allergy/intolerance records in a patient's health record and a patient who has no known allergy/intolerances, this activity diagrams shows the recording of an assertion that there are no known allergies/intolerances.

Allergy and Intolerance Information Not Asked

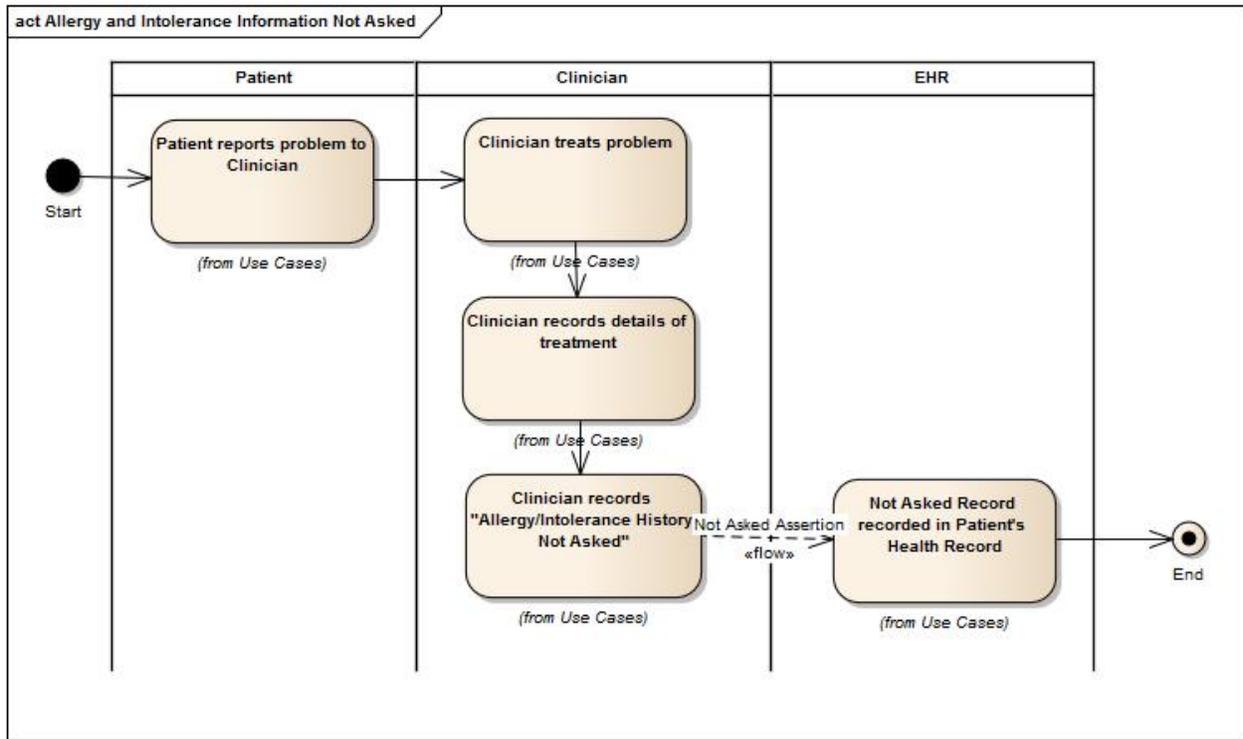


Figure 10 - Allergy and Intolerance Information Not Asked Activity Diagram

Similar to the No Known Information diagram, this diagram shows the recording of an assertion that the patient was not asked about allergy/intolerance information.

State Transition Diagram

The activities and information flows described in the above activity flows result in state transitions on the Adverse Sensitivity that are summarized in the following diagram

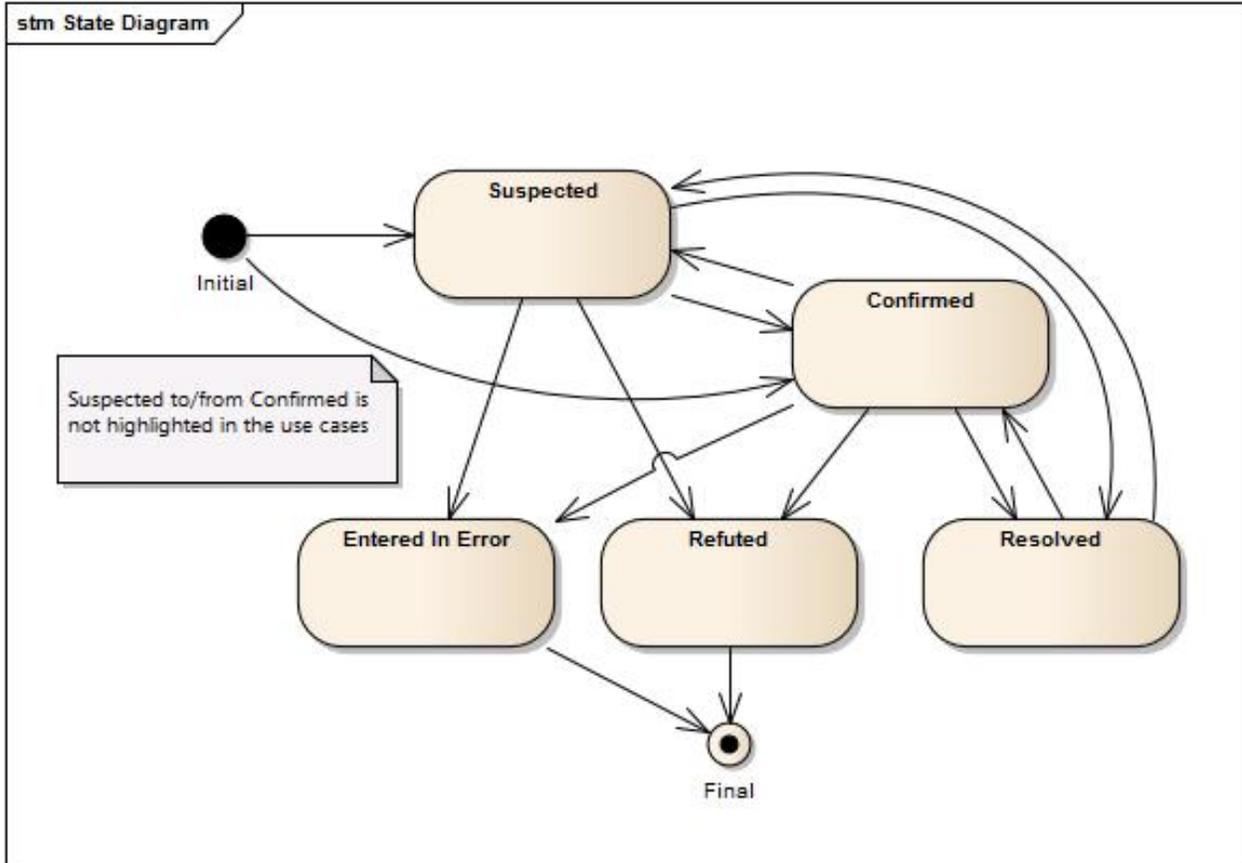


Figure 11 - Adverse Sensitivity State Transition Diagram

Information Model

Analysis of the described use cases and activity flows resulted in the following conceptual information model.

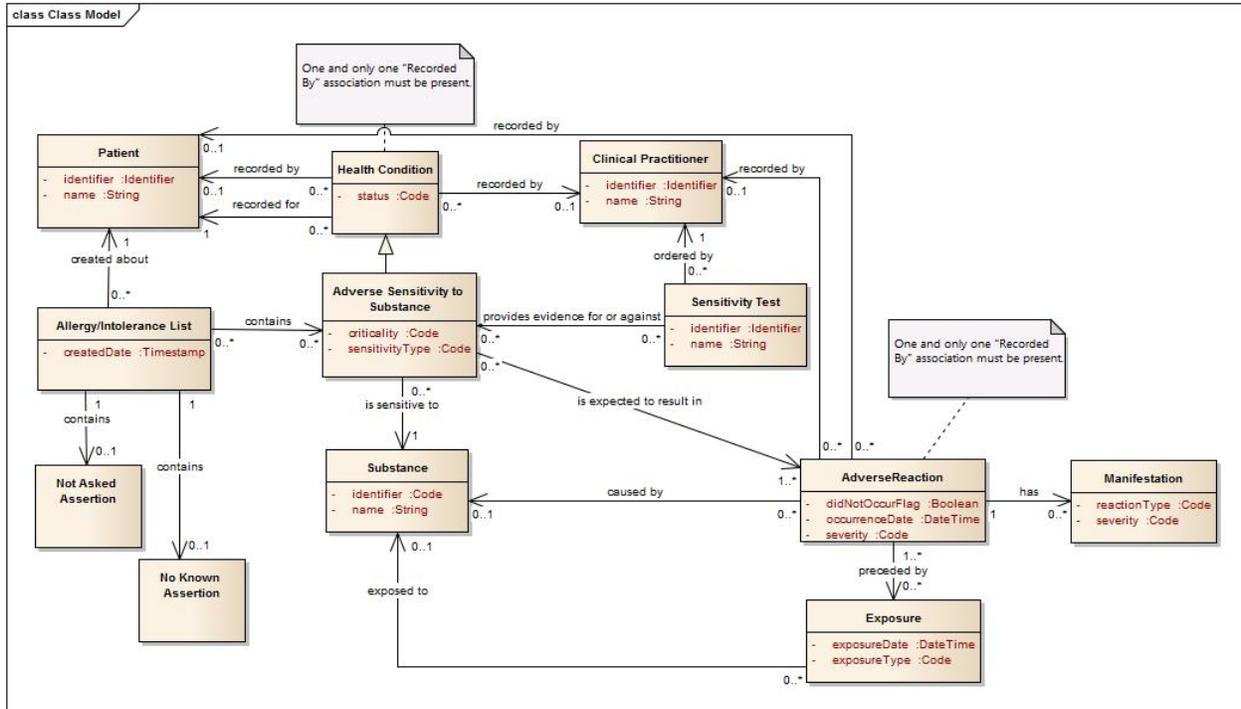


Figure 12 - Allergy/Intolerance Information Model

Definitions of the classes and attributes are documented in subsequent sections.

Attribute Definitions

Adverse Reaction

Attributes:

Name	Type	Definition
severity	Code	An overall assessment of the severity of the reaction.
didNotOccurFlag	Boolean	A flag that indicates that, although the patient came in contact with the substance, a reaction did not occur.
occurrenceDate	DateTime	When the reaction manifested itself.

Adverse Sensitivity to Substance

Attributes

Name	Type	Definition
criticality	Code	The potential seriousness of a

		future reaction. This represents a clinical judgment about the worst case scenario for a future reaction. It would be based on the severity of past reactions, the dose and route of exposure that produced past reactions, and the life-threatening or organ system threatening potential of the reaction type.
sensitivityType	Code	A code that indicates whether this sensitivity is of an allergic nature or an intolerance to a substance.

Allergy/Intolerance List

Attributes

Name	Type	Definition
createdDate	Timestamp	A timestamp that identifies when the list was created. This can be used to determine the currency of the data present in the list.

Clinical Practitioner

Attributes

Name	Type	Definition
identifier	Identifier	A string that can be used to uniquely identify the practitioner.
name	String	The name of the practitioner.

Exposure

Attributes

Name	Type	Definition
exposureDate	DateTime	A date (may be approximate) when the exposure occurred.
exposureType	Code	A code expressing how the exposure occurred. Example: Vaccination, Prescription Administration, Accidental

Health Condition

Attributes

Name	Type	Definition
status	Code	A code that indicates the current status of the concern. The states that a concern can enter depend on the precise subtype of concern.

Manifestation

Attributes

Name	Type	Definition
severity	Code	How severe the reaction was for this manifestation.
reactionType	Code	A code that indicates the specific adverse reaction that occurred. Example: Rash, Hives

No Known Assertion

Not Asked Assertion

Patient

Attributes

Name	Type	Definition
identifier	Identifier	A string given by a health authority that can be used to uniquely identify a patient.
name	String	The name of the patient, used to identify the specific patient.

Sensitivity Test

Attributes

Name	Type	Definition
identifier	Identifier	An identifier that references the results of the specific sensitivity test that associated with the adverse sensitivity.
name	String	A string that is normally used when referring to the given test.

Substance

Attributes

Name	Type	Definition
identifier	Code	A code that identifies the specific substance.
name	String	A string that is normally used when referring to the given substance.

Appendix A: Discussion of Criticality – Russell B. Leftwich, MD

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)

<http://www.uptodate.com/contents/leflunomide-in-the-treatment-of-rheumatoid-arthritis> (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 level s 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

Cast	Family	Given	MI	Gender	SSN	Phone
contact person	Contact	Carrie	C	F	555-22-2222	555-555-2010
family, daughter	Nuclear	Nancy	D	F	444-11-4567	555-555-5001
family, husband	Nuclear	Neville	H	M	444-11-1234	555-555-5001
family, son	Nuclear	Ned	S	M	444-11-3456	555-555-5001
family, wife	Nuclear	Nelda	W	F	444-11-2345	555-555-5001
next of kin (child)	Sons	Stuart	S	M	444-77-7777	555-555-2007
next of kin (other)	Relative	Ralph	R	M	444-99-9999	555-555-2009
next of kin (parent)	Mum	Martha	M	F	444-66-6666	555-555-2006
next of kin (spouse)	Betterhalf	Boris	B	M	444-88-8888	555-555-2008
patient, child	Kidd	Kari	K	F	444-55-5555	555-555-2005
patient, female	Everywoman	Eve	E	F	444-22-2222	555-555-2003
patient, male	Everyman	Adam	A	M	444-33-3333	555-555-2004

Table 2 - Healthcare Staff for Storyboards

Cast	Family	Given	MI	Gender	SSN	Phone
Admitting physician	Admit	Alan	A	M	666-66-6666	555-555-1005
Allergist/immunologist	Reaction	Ramsey	R	M	222-22-3333	555-555-1025
Anesthesiologist	Sleeper	Sally	S	F	222-66-6666	555-555-1012
Assigned practitioner	Assigned	Amanda	A	F	333-44-444	555-555-1021
Attending physician	Attend	Aaron	A	M	777-77-7777	555-555-1006
Authenticator	Verify	Virgil	V	M	999-99-9999	555-555-1008
Cardiologist	Pump	Patrick	P	M	222-33-4444	555-555-1027
Cardiovascular surgeon	Valve	Vera	V	F	222-33-5555	555-555-1028
Chaplain	Padre	Peter	P	M	333-77-7777	555-555-1020
Chief of staff	Leader	Linda	L	F	888-44-4444	555-555-1024
Chiropractor	Bender	Bob	B	M	222-66-6666	555-555-1053
Dentist	Chopper	Charlie	C	M	222-66-7777	555-555-1054
Dermatologist	Scratch	Sophie	S	F	222-33-6666	555-555-1029
<i>Dietitian</i>	<i>Chow</i>	<i>Connie</i>	<i>C</i>	<i>F</i>	<i>333-55-5555</i>	<i>555-555-1018</i>
Electro-physiologist	Electrode	Ed	E	M	333-77-7777	555-555-1020
Emergency medicine specialist	Emergency	Eric	E	M	222-33-7777	555-555-1030
Endocrinologist	Hormone	Horace	H	M	222-33-8888	555-555-1031
Family practitioner	Family	Fay	F	F	222-33-9999	555-555-1032
Gastroenterologist	Tum	Tony	T	M	222-44-2222	555-555-1033

Cast	Family	Given	MI	Gender	SSN	Phone
Geriatrician	Sage	Stanley	S	M	222-44-3333	555-555-1034
Healthcare provider	Seven	Henry	L	M	333-33-3333	555-555-1002
Hematologist	Bleeder	Boris	B	M	222-44-3344	555-555-1035
infectious disease specialist	Pasteur	Paula	P	F	222-44-5555	555-555-1036
Informal Career	Comrade	Connor	C	M	333-77-7777	555-555-1020
Intern	Intern	Irving	I	M	888-22-2222	555-555-1022
Internist	Osler	Otto	O	M	222-44-6666	555-555-1037
IT System Administrator	Admin	I.	T.	M	333-33-3333	555-555-1002
Lab technician	Beaker	Bill	B	M	333-44-4444	555-555-1017
Laboratory Specimen Processor	Spinner	Sam	S	M	333-45-4545	555-555-1020
Nephrologist	Renal	Rory	R	M	222-44-7777	555-555-1038
Neurologist	Brain	Barry	B	M	222-44-8888	555-555-1039
Neurosurgeon	Cranium	Carol	C	F	222-44-9999	555-555-1040
Nursing assistant	Barton	Clarence	C	M	222-99-9999	555-555-1015
OB/GYN	Fem	Flora	F	F	222-55-2222	555-555-1041
Occupational therapist	Player	Pamela	P	F	222-77-6666	555-555-1059
Oncologist	Tumor	Trudy	T	F	222-55-3333	555-555-1042
Ophthalmologist	Vision	Victor	V	M	222-55-4444	555-555-1043
Optometrist	Specs	Sylvia	S	F	222-66-9999	555-555-1056
Orthodontist	Brace	Ben	B	M	222-66-8888	555-555-1055

Cast	Family	Given	MI	Gender	SSN	Phone
Orthopedic surgeon	Carpenter	Calvin	C	M	222-55-5545	555-555-1044
Otolaryngologist (ENT)	Rhino	Rick	R	M	222-55-6666	555-555-1045
Pastoral Care Director	Sacerdotal	Senior	S	M	333-77-7777	555-555-1020
Pathologist	Slide	Stan	S	M	222-44-4444	555-555-1010
Pediatrician	Kidder	Karen	K	F	222-55-7777	555-555-1046
Pharmacist	Script	Susan	S	F	333-22-2222	555-555-1016
Physical therapist	Stretcher	Seth	S	M	222-77-8888	555-555-1060
Physician	Hippocrates	Harold	H	M	444-44-4444	555-555-1003
Physician assistant	Helper	Horace	H	M	222-66-5555	555-555-1052
Plastic surgeon	Hollywood	Heddie	H	F	222-55-8888	555-555-1047
Podiatrist	Bunion	Paul	B	M	222-77-2222	555-555-1057
Primary care physician	Primary	Patricia	P	F	555-55-5555	555-555-1004
Psychiatrist	Shrink	Serena	S	F	222-55-9999	555-555-1048
Psychologist	Listener	Larry	L	M	222-77-3333	555-555-1058
Pulmonologist	Puffer	Penny	P	F	222-66-2222	555-555-1049
Radiologist	Curie	Christine	C	F	222-55-5555	555-555-1011
Referring physician	Sender	Sam	S	M	888-88-8888	555-555-1007
Registered nurse	Nightingale	Nancy	N	F	222-88-8888	555-555-1014
Resident	Resident	Rachel	R	F	888-33-3333	555-555-1023
Rheumatologist	Joint	Jeffrey	J	M	222-66-3333	555-555-1050

Cast	Family	Given	MI	Gender	SSN	Phone
Social worker	Helper	Helen	H	F	333-66-6666	555-555-1019
Specialist	Specialize	Sara	S	F	222-33-3333	555-555-1009
Surgeon	Cutter	Carl	C	M	222-77-7777	555-555-1013
Transcriptionist	Enter	Ellen	E	F	333-77-7777	555-555-1020
Urologist	Plumber	Peter	P	M	222-66-4444	555-555-1051

Appendix C: Glossary

HL7 Allergy and Intolerance Glossary		
TERM	DEFINITION	SOURCE
Adverse Effect	A harmful or abnormal result. An adverse effect may be caused by administration of a medication or by exposure to a chemical and be indicated by an untoward result such as by illness or death.	http://www.medterms.com/script/main/art.asp?articlekey=12073
Adverse Event	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. An adverse event (AE) can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.	http://ichgcp.net/1-glossary
Adverse Event	<p>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.</p> <p>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.</p> <p>Post-marketing/European Union:</p>	<p>HL7 Glossary: http://www.hl7.org/documentcenter/public_temp_872FC4C8-1C23-BA17-0CB2BD4A93A6DD80/calendarofevents/FirstTime/Glossary%20of%20terms.pdf</p>

	Any undesirable experience occurring to a patient treated with a pharmaceutical product whether or not considered related to the medicinal product.	
Adverse Reaction	An undesirable physiological effect resulting from exposure to a substance.	Reference: Discussion with Russell Leftwich MD (Allergist), Mark Janczewski MD and Elaine Ayres (NIH) at HL7 Phoenix Jan 2013. Updated on 1/19/2014 based on ballot comments.
Adverse Sensitivity	A condition expected to result in an adverse reaction to an amount of a substance that would not produce a reaction in most individuals.	Reference: Discussion with Russell Leftwich MD (Allergist), Mark Janczewski MD and Elaine Ayres (NIH) at HL7 Phoenix Jan 2013. Updated on 1/19/2014 based on ballot comments.
Allergy	An exaggerated immune response or reaction to a substance that is generally not harmful [to most people] The manifestation of an allergy includes a variety of physiologic responses (e.g. rash, itching, hypotension, anaphylaxis) and can be dependent on the route of exposure (inhalation, skin contact, ingestion).	(Ref: MedLine Plus, US National Library of Medicine, NIH).
Allergy Status	An allergy could be further categorized as: Confirmed - via laboratory testing or witnessed observation or other strong evidence, or Suspected (Unconfirmed) - Patient reported but not further verified by clinical	Reference: Discussion with Russell Leftwich MD (Allergist), Mark Janczewski MD and Elaine Ayres (NIH).

	history, diagnostic testing or is uncertain.	
Antigen	Any substance (as an immunogen or a hapten) foreign to the body that evokes an immune response either alone or after forming a complex with a larger molecule (as a protein) and that is capable of binding with a product (as an antibody or T cell) of the immune response	Medline Plus/Merriam Webster Medical Dictionary
Anaphylaxis	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.	Mayo Clinic - Definition by Mayo Clinic staff http://www.mayoclinic.com/health/anaphylaxis/DS00009
Criticality	The potential seriousness of a future reaction. This represents a clinical judgment about the worst case scenario for a future reaction. It would be based on the severity of past reactions, the dose and route of exposure that produced past reactions, and the life-threatening or organ system threatening potential of the reaction type. Criticality is an attribute of the allergic condition, not the reaction(s).	Russell Leftwich, MD (Allergist) and HL7 Allergy and Intolerance WG Subject Matter Expert
Device, Medical	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).	HL7 Glossary: http://www.hl7.org/documentcenter/public_temp_872FC4C8-1C23-BA17-0CB2BD4A93A6DD80/calendarofevents/FirstTime/Glossary%20of%20terms.pdf
Domain Analysis Model (DAM)	The analysis of a particular topic or domain.	HL7 Glossary: http://www.hl7.org/documentcenter/public_temp_872FC4C8-1C23-BA17-0CB2BD4A93A6DD80/calendarofevents/FirstTime/Glossary%20of%20terms.pdf

		ndarofevents/FirstTime/Glossary%20of%20terms.pdf
Electronic Health Record	An Electronic Health Record (EHR-S) is a comprehensive, structured set of clinical, demographic, environmental, social, and financial data and information in electronic form, documenting the health care given to a single individual.	(ASTM E1769, 1995)
Electronic Health Record System	A system for recording, retrieving and handling information in electronic health records.	ISO 18308, [ISO/EN 13606-1:2008]
Health Condition	Aspect of a person or group's health that requires some form of intervention. These interventions could be anticipatory or prospective, such as enhancing wellness, wellness promotion or illness prevention (e.g., immunization).b) symptoms, health problems (not yet diagnosed), diagnoses (known or provisional), e.g., diabetes, or physiological changes that affect the body as a whole or one or more of its parts, e.g., benign positional vertigo, and/or affect the person's well-being, e.g., psychosis, and/or affect the person's usual physiological state, e.g., pregnancy, lactation.	ISO/TR 12773-1
Hypersensitivity	Exposure to an antigen which produces an immediate or almost immediate reaction.	Medline Plus/Merriam Webster Medical Dictionary
Intolerance	A non-immunological adverse physiological sensitivity to a substance. It may be manifested by an inability to endure, withstand, absorb, or metabolize a substance (e.g. lactose).	Reference: Discussion with Russell Leftwich MD (Allergist), Mark Janczewski MD and Elaine Ayres (NIH) at HL7 Phoenix Jan 2013.)
Manifestation	A perceptible, outward, or visible expression (as of a disease or abnormal condition).	Medline Plus/Merriam Webster Medical Dictionary

Personal Health Record	Health record, or part of a health record, for which the subject of care or a legal representative of the subject of care is the data controller	ISO 18308
Preference	Related to Dietary Orders - Preferences consist of likes, dislikes, substitutions, and complementary foods. Preferences are diet orders, effectively from the patient, but transmitted from the ward. They are subject to change. Preferences are independent of the diet order and do not change when the order changes.	HL7 Glossary: http://www.hl7.org/documentcenter/public_temp_872FC4C8-1C23-BA17-0CB2BD4A93A6DD80/calendarofevents/FirstTime/Glossary%20of%20terms.pdf
Reaction	Bodily response to or activity aroused by a stimulus: an action induced by vital resistance to another action ; especially : the response of tissues to a foreign substance (as an antigen or infective agent).	Medline Plus/Merriam Webster Medical Dictionary
Reconciliation	Display the data from two or more sources in a manner that allows a user to view the data and their attributes, which must include, at a minimum, the source and last modification date of the information. User is able to merge and remove individual data and then review and validate the accuracy of a final set of data elements.	ONC Stage II Standards and Certifications 2014 Final Rule: http://www.gpo.gov/fdsys/pkg/FR-2012-09-04/pdf/2012-20982.pdf
Resolve	To undergo resolution—used especially for disease or inflammation	Medline Plus/Merriam Webster Medical Dictionary
Substance	A substance is a physical material and for purposes of this domain analysis model can mean a drug or biologic, food, chemical agent, plants, animals, plastics etc.	HL7 Patient Care WG on Allergies and Intolerances 2012. Updated based on ballot comments 1/19/14.
Triggering Agent	The substance causing the adverse sensitivity.	HL7 Patient Care WG on Allergies and Intolerances 2012

Appendix D: Acronyms

Acronym	Meaning	Note
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Acronym	Meaning	Note
CPOE	Computerized Provider Order Entry (System)	
EHR-S	Electronic Health Record	
EHR-S	Electronic Medical Record	
LIC	Licensed Healthcare Provider	
PHR	Personal Health Record	
RD	Registered Dietitian (or Healthcare Provider (PROV-RD))	See Actor/Roles definition for clarification.

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