**HL7 Patient Care Work Group**

**Allergy/Intolerance/Adverse Reaction Topic Sub-Group Meeting Minutes**

**Date: April 26, 2012**

Co-Chairs: Stephen Chu, Hugh Leslie, Elaine Ayres Scribe: Elaine Ayres

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| --- | --- | --- | --- |
| **Name** | **Organization** | **E-mail** | **Present on 4/26/12** |
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| Ben Loy |  |  |  |
| Bill Gregory | Patient Safety |  | X |
|  |  |  |  |

**Agenda for April 26, 2012**

1. Review and approve the minutes for April 12, 2012 meeting
2. Review status of Project Scope Statement
3. Review status of DSTU Extension Withdrawal Request
4. EHR-S FM r2 requirements – mapping to use cases – Kevin (postponed)
5. Review assigned use cases
   1. Stephen and Hugh – Observed medication reaction
   2. Russ – Creating and maintaining an allergy list
   3. Stephen and Hugh – Unable to determine allergy vs. intolerance
6. CSCR-044 Causative Agent - Clinical Statement change request - Stephen
7. Agenda issues for Vancouver WG meeting (Wednesday, May 16 – Q4)
8. Plan the agenda for the **May 10**  conference call (call cancelled)

**Minutes** –

Minutes of the *April 12, 2012* conference call –

Motion: Russ/Carolyn Abstain – 0 , No – 0, Yes - 5

**Project Scope Statement –**

On TSC Agenda - April 30, 2012

**DSTU Extension**  -

Requires vote to withdraw DSTU extension request to the TSC. Voted at 4/12/12 meeting.

On TSC Agenda – May 7, 2012

**Review of Use Cases**

The table below lists the current use cases, and the individuals assigned to write the use case(s).

1. **USE CASE Adverse Reaction to Medications (observed event) (Stephen and Hugh)**

FINAL VERSION as of May 1, 2012 based on discussions.

**Use Case Title**

Adverse Reaction to Medications (observed event)

**Use Case Description**

The purpose of this use case is to support the documentation of allergy/intolerance and adverse reaction to medications in hospital clinical information systems/EMRS; and to support the generation and exchange of such information in a hospital discharge summary.

**Conditions**

A patient suffering from adverse reaction to prescribed medication is assessed, diagnosed and treated for the adverse reaction.

**Exclusions**

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

**Preconditions**

Patient presented to hospital with signs and symptoms of adverse reactions to medication(s).

The hospital uses electronic medical record systems supporting the documentation of the adverse reaction event, management and revision of allergy/intolerance list

Hospital electronic clinical information system/EMRS capable of generating and transmitting electronic discharge summary

**Sequence of Steps**

Patient presenting to ED

Patient was assessed with full medical history taking by attending physician

Patient condition was diagnosed, treatment was given

Access to hospital EMRS by attending physician

No pre-existing allergy/intolerance information on patient available

Documentation of presenting problem, medical history, medication history, treatment and outcomes with creation/update of allergy/intolerance lists and medical alert on allergy/intolerance to medication in hospital clinical information system or EMRS

Discharge summary generated using hospital clinical information system or EMRS

**Post Conditions**

Updated EMRS record with allergy/intolerance list, adverse reactions and medical alerts

Hospital discharge summary with allergy/intolerance and adverse reaction information and transmitted to patient’s primary care physician/GP

Allergy/intolerance and adverse reaction information also transmitted patient specified pharmacy(ies) and PHR where applicable

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

**Use Case Scenarios**

A 60-year old man with extensive skin rash presents himself at the ED of a local hospital.

His *presenting complaints* include:

Rash started on the back and palm of his hands spreading quickly to the arms, neck, face and trunk.

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*:

Hypercholesterol aemia 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 1o 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 family doctor/GP)

He denied taking any other medications including OTC or other non prescribed medications.

*Allergy/Intolerance List/Alert*:

Hospital EMRS does not have pre-existing allergy/intolerance information on patient

*Physical Examinations*:

Blood pressure: 135/80 mmHG

Heart: rate = 86/min, no murmur, no added HS; ECG = AF, no ischaemia

Respiratory, CNS, Abdomen/GI, Genito-urinary: NAD

*Blood Tests*:

BSL = 5.8 mmol/L

U+E = normal

LFT = normal

*Diagnosis*:

Patient was diagnosed by the attending 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 sulphonylurea (Glicazide).

*Treatment*:

Patient was admitted into the medical unit of the hospital where his condition was managed by physician of general medicine clinical unit

The glicazide was stopped

Symptomatic treatment including oral antihistamines, analgesics, local skin care, and soothing mouthwashes

*Outcomes*:

The erythema multiforme resolved.

The adverse reaction to glicazide was documented in patient’s medical record.

The allergy/intolerance list was updated with inclusion of glicazide as a trigger to adverse reactions

On discharge, a discharge summary was generated with a summary of the reasons for encounter, treatment given, outcomes and revised allergy/intolerance list and clinical alert.

Discharge summary with allergy/intolerance list and adverse reaction information on glicazide was transmitted to patient’s primary care physician

Allergy/intolerance list and adverse reaction information on glicazide was also transmitted to patient specified pharmacy(ies) and PHR.

**References:**

<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>

<http://www.rdehospital.nhs.uk/docs/patients/diabetes/RDE%20diabetes%20-%20type%202%20glycaemia%20-%20sulphonylureas.pdf>

1. **USE CASE: Creation and Maintenance of List of Allergic or Intolerance Conditions (Russ)**

FINAL Version as of 5/8/2012 based on discussion.

## **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.

Conditions

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

Exclusions

Evaluation by allergy specialist or confirmation of reactions by testing or direct challenge.

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.

Use Case Sequence of Steps

1. List of allergies and intolerances is created on intake by new PCP
2. Previous record is reviewed and reconciled with patient history to update list
3. Patient is seen by PCP with reaction to newly prescribed medication. List is updated.
4. Patient is given new medication by another provider and has reaction that results in ED visit.
5. Summary is sent to PCP by ED with new allergy or intolerance added to list (and pharmacy and PHR)
6. PCP (Pharmacy and PHR) reconciles list of allergies and intolerances and updates list.

Post Condition

Reconciled list of allergy and intolerances is part of patient record(s).

Use Case Scenario

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

Eve Everywoman notes that at the age of four, she was given penicillin for strep throat and subsequently developed severe hives. According to her mother, 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 during this initial visit reveals an itchy red weeping rash on Eve’s face, neck and shoulders where she had applied a promotional sample of sunscreen last month. The rash appeared the following day, and resolved after about a week. She did not take any medication for these symptoms. This does not occur when she uses her favorite brand, including when she used it four days ago.

Six months later, George Gynecologist gives Eve trimethoprim/sulfamethoxazole for dysuria. After four days, Eve calls to report vaginal itching and is given lotrimin. On day seven, Eve develops an itchy rash of purplish hives, sore red tongue, and red eyes over three days (while still taking the antibiotic). Eve calls her primary care provider who advises her to come in for an office visit. The primary care provider diagnoses an allergy to sulfa drugs and tells her to stop the trimethoprim/sulfamethoxazole. She was advised to take diphenhydramine as needed every six hours and all of her symptoms resolved over about a week. Sulfa allergy is added to the allergy list.

Three months after the diagnosis of the sulfa allergy, Eve visits Dan Dermatologist 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 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 Eve is told she is allergic to erythromycin. Her symptoms had resolved by the time she left the emergency department. The emergency room summary has downloaded the allergy list from the local Health Information Exchange as a CCD and has added an allergy to erythromycin.

The primary care provider reviews her account of the episode and reviews the summary from the emergency department. He advises that this episode is an intolerance related to dose and updates the allergy list. The erythromycin allergy is changed to “inactive” and an erythromycin intolerance is added to the list.

1. **USE CASE: Unable to Determine Allergy Vs. Intolerance (Stephen and Hugh)(defer)**

***Discussion deferred***

**Use Case Description**

The purpose of this use case is to support the documentation of the assertion Unable to determine allergy versus intolerance (to seafood) for a patient who experienced adverse reactions several hours after ingestion of a seafood dinner.

The information is then captured in hospital clinical information systems/EHRS; and to support the generation and exchange of such information in a hospital discharge summary.

**Conditions**

A patient experienced signs and symptoms of adverse reactions several hours after ingestion of seafood dinner. The patient presented himself at the Emergency Department for treatment and is assessed for history of allergy/intolerance as part of medical history assessment and examination procedures.

**Exclusions**

Patient’s adverse reactions which can be positively associated as allergy or intolerance reaction to one or more seafood ingested prior to onset of the reactions.

**Preconditions**

Patient presented to hospital with for care/treatment.

The hospital uses electronic medical record systems supporting the documentation of the adverse reaction event, management and revision of allergy/intolerance list

Hospital electronic clinical information system/EHRS capable of generating and transmitting electronic discharge summary

**Sequence of Steps**

1. Patient presenting to ED
2. Patient was assessed with full medical history taking and physical examination by attending physician
3. Patient condition was diagnosed, treatment was given
4. Documentation of presenting problem, medical history, medication history, treatment and outcomes with creation/update of allergy/intolerance lists in clinical information system or EHRS
5. Discharge summary generated using hospital clinical information system or EHRS

**Post Conditions**

Updated EHRS record with “Unable to determine allergy versus intolerance” to a number of seafood entry to allergy/intolerance list

Hospital discharge summary includes entry on “Unable to determine allergy versus intolerance” to a number of seafood

**Use Case Scenarios**

A 52-year old male business executive had dinner at a seafood restaurant shortly before boarding a one-hour interstate flight to return home. The dinner consisted of tuna salad, mixed seafood platter (prawn, oyster, crabs, and snapper and salmon sashimi) and a glass of white wine. Shortly after arrived at home he began to feel very unwell. He took a taxi from home and presented himself at the ED of local hospital requesting medical care.

Patient had previously consumed seafood but not raw fish or mixed cooked and raw fishes in a single meal.

His *presenting complaints* include:

Patient began to fell unwell minutes after arriving home. Time lapse between food ingestion and onset of symptoms appropriately 3.5 to 4 hours

Nausea, vomiting, diarrhoea, abdominal pain, urticaria and itchiness

*Medical History*:

Mild hypertension

Hypercholesterolaemia

Denied **any known history of allergy or intolerance** to any medication or substance

Denied any relevant family medical history including any know allergy or intolerance.

*Medications*:

Glucosamine sulphate: 50 mg once daily

Simvastatin 20 mg at night

*Physical Examinations*:

Blood pressure: 148/83 mmHg (likely to be stressed related)

Heart: rate = 84/min, no murmur, no added HS, ECG = sinus rhythm, no ischaemia

Mild nausea, vomiting, diarrhoea,

Abdomen: soft, hyperactive bowel sounds, abdominal cramps

Respiratory: mild dyspnoea, no wheezing, no cyanosis

Urticarial skin rash over face, neck, chest, and upper back; itchiness

*Tests*:

No food specimen available for toxicology study

Bloods: normal U+E/RFT; normal haematocrits

X-Ray Abdomen supine & erect views: no abnormality detected

*Diagnosis*:

Given the mixed seafood meal and no food specimen available for toxicology tests, a definitive diagnosis is unlikely

Possible seafood allergy

Possible scombroid poisoning (given ingestion of tuna and red skin snapper prior to onset of symptoms)

*Treatment*:

Antihistamine: loratidine 10mg

Ranitidine 150mg

*Outcomes*:

Signs and symptoms resolve gradually after treatment with antihistamine (loratidine) and H2 receptor blocker (Ranitidine).

A definitive diagnosis could be established in ED, it was unclear whether this was a case of seafood allergy or scomborid fish poisoning.

The allergy/intolerance list was updated with entry of “Unable to determine allergy versus intolerance” to a number of seafood.

Patient discharged home after several hours of observation and clinically determined that the offending signs and symptoms had subsided

Hospital EHRS on this patient is updated with statement on “Unable to determine allergy versus intolerance” to a number of seafood

Discharge summary sent to GP including statement on “Unable to determine allergy versus intolerance” to a number of seafood.



**CSCR-044 Causative Agent - Clinical Statement change request - Stephen**

Wording discussed at the February 16th meeting:

Clinical Statement change request from the Clinical Statement WG: inclusion of “causative agent/allergen” in CS Model – see HL7 wiki URL:  <http://wiki.hl7.org/index.php?title=CSCR-044_Causative_Agent>

## Issue  - Shortcut participation of a causative agent associated with an observation, e.g. allergy caused by peanuts.

## Old Recommendation  - Add proposed Causative Agent (CAUS) participation from Observation to Agent choice box (proposed in CSCR-043)

## Rationale  - An allergy/intolerance is commonly represented as an observation/condition and the associated causative agent. To represent this simple/shortcut allergy representation, the causative agent participation directly associated from the observation is required

Stephen’s  suggested wording  – modify statement to:

*“Allergy/Intolerance is a condition in which an individual has a predisposition to adverse reactions of the allergic/intolerance reaction type. An adverse reaction is triggered by exposure of such individual to a susceptible agent/substance. The agent/substance is the cause or suspected to be the cause (until validated/confirmed by diagnostic investigations) of the adverse reaction given the condition.”*

CS requires PCWG to submit a project proposal for the change request to be initiated. Further discussions are required.

ACTION – Stephen will follow-up with the Clinical Statement Work Group.

**Agenda for WGM Vancouver, Wednesday Q4 May 17, 2012**

1. Review agenda for meeting and add other issues as needed
2. Review and approve the minutes for April 26, 2012 meeting
3. Review status of Project Scope Statement - Elaine
4. Review status of DSTU Extension Withdrawal Request - Elaine
5. Review of current functional model - Jean
6. Review of allergy use case list
7. Review assigned use cases
8. Confirm ongoing meeting day and time for conference calls (currently every other Thursday at 5 PM EDT). Next call would be on May 24th.
9. Plan the agenda for the next conference call