HL7 RCRIM WG

FHIR AdverseEvent Resource

CALL MINUTES: Friday, June 2, 2017

Meet online at www.webex.com, meeting number: 196 412 889
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Project Wiki

http://wiki.hl7.org/index.php?title=FHIR_Adverse_Event_Resource

References

1) Search the FDA Acronyms & Abbreviations Database: http://www.fda.gov/AboutFDA/FDAAcronymsAbbreviations/default.htm
2) FHIR Conformance Rules: http://hl7.org/fhir/conformance-rules.html
   a) See 1.12.2 Cardinality

Agenda

AGENDA:

1. Review minutes from April 7: http://wiki.hl7.org/images/c/c3/FHIR_AdverseEvent_Resource_Agenda_and_Minutes_2017-04-07.pdf
2. Update on Madrid presentation of AE resource to BRR (Rik Smithies)
3. Review of comments from Clinicians on FHIR
4. Review GFORGE requests
5. Other requests for update to resource
6. Schedule for upcoming meetings

Minutes

1. Minutes Approval: http://wiki.hl7.org/images/c/c3/FHIR_AdverseEvent_Resource_Agenda_and_Minutes_2017-04-07.pdf
2. Ownership of FHIR AE resource
3. Madrid presentation to BRR: Rik presented. General discussion about next steps.
4. Clinicians on FHIR notes: http://wiki.hl7.org/index.php?title=Clinician_on_FHIR_-_May_2017_Madrid,_Spain
   a. See use cases at the end of the minutes
   b. Additional comments on AE FHIR resource beyond minutes. Modeling an AE was the topic, based on the use cases. (Add use cases here). What is the adverse event? Is it the injury or harm, or is it the aberrant work flow that causes the harm? Is the adverse reaction the adverse the event? The adverse event is the aberrant work flow that leads to the harm.
   c. Patient falls out of bed and breaks the wrist. The adverse event is leaving the bed rails down.
   d. Allergic reaction to a new med – there was no adverse work flow, but there was still an allergic reaction. The near miss hard to model. If the adverse event is the aberrant work flow then easier to model. The injury that results is not the adverse event. It was hard to fit the clinical trial into this new model.
      i. Terminology – what to use in SNOMED CT. May not be a perfect match. Remove binding temporarily and come up with a specific value set. Change to the actual event that occurred with an example. GFORGE for change.
   e. Event binding "Type of the event itself in relation to the subject. Look at vocab bindings. What about two inappropriate drugs together. May be in the clinical findings. Look at 8 use cases and see if we can find the adverse.
      i. Transplant – graft vs. host disease. Meds can be captured re graft vs. host disease. Scoring of severity – where do we put that. Sometimes such a reaction is a good thing.
5. GFORGE Requests"
   a. **13308:(Resolved)**
      i. **http://gforge.hl7.org/gf/project/fhir/tracker/?action=TrackerItemEdit&tracker_item_id=13308&start=0**
   b. **13309: (Resolved)**
      i. **http://gforge.hl7.org/gf/project/fhir/tracker/?action=TrackerItemEdit&tracker_item_id=13309&start=0**

c. **13310:** **http://gforge.hl7.org/gf/project/fhir/tracker/?action=TrackerItemEdit&tracker_item_id=13310&start=0**
d. **13302:** **http://gforge.hl7.org/gf/project/fhir/tracker/?action=TrackerItemEdit&tracker_item_id=13302&start=0**
e. **13312:(Resolved)**
    i. **http://gforge.hl7.org/gf/project/fhir/tracker/?action=TrackerItemEdit&tracker_item_id=13312&start=0**

6. Adverse Reaction resources – need clear modeling.

If the adverse event represent the actual event that led to something and then represent the adverse reaction is what happened? Reaction – represents the causality. The AE is the administration of penicillin, and then the reaction is the anaphylaxis. The resulting condition needs to clearly point to adverse reactions as well as other things.

Take a look at resulting condition. Outcome and result are blending together.

ACTION: Elaine will take a look at use cases used for Clinicians on FHIT to look at terminology for the element AdverseEvent.event. The wording needs to be updated and the use of SNOMED CT clinical findings should be changed to a specific value set.

Agenda for Next Meeting:

1. Review minutes from June 2
2. Review of action items
3. Other issues
    a. Tracking issues in G-FORGE and Zulip
4. Agenda items for next meeting

Additional notes:

Use Cases from Clinicians on FHIR in Madrid – May 2017

Clinicians on FHIR – Adverse Event Scenarios
May 2017 - Madrid

FHIR AE Resource is in "Current Build" : http://build.fhir.org/adverseevent.html

For GFORGE Tracking – use BiomedRR WG (formerly RCRIM)

Scenario One – Procedural adverse event with resulting complication

Scenario 1a – Procedure adverse event with resulting injury
Mrs. Jones is a 68 year old female was scheduled for a routine colonoscopy in an outpatient surgery center. Her current medical history included hypertension for which she took Cozaar 50 mg daily, and Naproxen 500 mg daily for her osteoarthritis.

The patient followed the usual bowel preparation routine (polyethylene glycol solution) and the procedure began with the introduction of the endoscope by the gastroenterologist, Dr. Colon. The ascending and transverse colon showed no significant findings but the presence of a .5 cm sessile adenoma in the sigmoid

colon merited removal. The gastroenterologist performed a polypectomy with electrocautery and completed the procedure.

Mrs. Jones was discharged two hours after the procedure. One the second day after the procedure the patient experienced symptoms of fever, localized abdominal pain, localized peritoneal signs and leukocytosis. Upon examination by Dr. Colon, Mrs. Jones was found to have an electrocoagulation injury to the bowel wall that caused a transmural burn and localized peritonitis without evidence of perforation on radiographic studies. Her postpolypectomy electrocoagulation syndrome was managed with intravenous hydration, antibiotics, and nothing by mouth until the symptoms subsided.

Scenario Two – Device Adverse Event

On December 12, 2005, J. Doe, a 54 year old female was admitted to the Outpatient Surgery Center for the placement of a Medical Corporation X, Model LS 4700, implantable pain pump. In surgery, the pain pump was implanted without difficulty and was determined to be functional.

After the procedure the patient was transferred to the recovery area for stabilization. In the recovery room, the anesthesiologist, Dr. Zoe, initiated the programming of Ms. Doe's implanted pump. During this set-up procedure the pump stopped functioning and the pump's visual display went blank. The anesthesiologist was unable to troubleshoot the cause of the device failure, nor restore its function. The patient was informed of the device failure and opted to return to the O.R. the next day for the removal of the defective device and placement of a new pain pump. The second Model LS 4700 implantable pain pump was implanted and completed its programming process without difficulty.

Scenario Three – Drug-Drug Interaction

A 39-year-old female was evaluated for episodes of syncope and light-headedness that began two days prior to her hospital admission. The history was consistent with possible cardiovascular causes, and the patient was admitted and placed on telemetry where the preceding rhythm strip was observed.

Ten days prior to admission she had been prescribed terfenadine (Seldane—an antihistamine) 60 mg twice-a-day and cefaclor (Ceclor—a cephalosporin antibiotic) 250 mg three-times-a-day. On the eighth day of terfenadine therapy the patient began a self-medicated course of ketoconazole (Nizoral—an azole antifungal) at 200 mg twice-a-day for vaginal candidiasis. She was also taking medroxyprogesterone acetate at a dosage of 2.5 mg a-day. Upon admission to the hospital the patient was noted to have a QTc interval of 655 milliseconds (normal is less than 440 milliseconds). During the hospitalization the patient experienced near syncopal episodes associated with torsades de pointes noted on telemetry.

After discontinuing the medications, the QTc interval normalized. She had no further episodes of torsades de pointes, and she was discharged with no recurrence of syncope.

Monahan BP, Ferguson CL, Cleave ES, Lloyd BK, Troy J, Cantilena LR. Torsade de pointes occurring in association with terfenadineuse. JAMA 1990;264:2788–2790.

Scenario Four – Fall with Injury

A 75 year old woman Mrs. Jones was admitted to an in-patient oncology service for treatment of Non-Hodgkins lymphoma because of a persistent fever. The patient used a cane for ambulation because "she felt unsteady on her feet" and therefore, a fall-risk protocol was implemented.

During the second night of her in-patient stay Mrs. Jones awoke and rather than ringing the nurse call bell, decided to ambulate on her own to the bathroom. After getting out of bed, Mrs. Jones fell and broke her hip. The broken hip extended Mrs. Jones' stay by one week and required an admission to a rehabilitation facility for physical therapy. The hospital documented the incident in the occurrence reporting system, and Mrs. Jones' care and treatment was documented in her electronic health record.

Scenario Five – Near Miss

Annie Patient a 78 year old woman is scheduled for a hip replacement. After her arrival in the operating room but before induction of anesthesia it is discovered that the size of prosthesis that was felt to be most appropriate has not been sent to the OR, although the size above and below are available. The missing size prosthesis is brought to the OR from central supply and arrives before anesthesia has begun.

Scenario Six – Wrong medication administration with No Harm

Arnold Bear, a 70 year old male patient hospitalized for an elective hip replacement is inadvertently given a capsule containing 3,000 IU of Vitamin D intended for a patient in the adjacent room who is receiving a daily Vitamin D supplement because of Vitamin D deficiency in the past.

Mr. Bear experiences no symptoms and has no conditions which would be affected by Vitamin D intake. The inadvertent administration of Vitamin D is documented in his medication administration record and in a clinical note in his record. An incident report is completed in the hospital's incident reporting system.

Scenario Seven – Causality

A 64 year old woman was experiencing profound dryness of the eyes resulting in blurred vision. A treatment regimen with tear duct plugs and Xiidra, a twice daily ocular solution. Following a week of this regimen, the patient experienced a yellowish exudate from both eyes, with inflammation of the eye lid. An examination by a lacrimal specialist revealed calcium deposits in tear glands, and recommended that the Xiidra be stopped. The tear duct plugs were dissolvable and remained in place.

After stopping the Xiidra, the symptoms abated after 72 hours. The patient filed a MedWatch report detailing the symptoms experienced with Xiidra. (Note that a patient reported event automatically assumes causality).

Scenario Eight – Clinical Trial

Clinical Trial – Significant Adverse Event
This scenario involves a phase 2, clinical study evaluating the safety and efficacy of a new oral agent administered daily for treatment of severe psoriasis unresponsive to FDA-approved treatments. There are two arms of the study – subjects receiving the new oral agent or a placebo. Only the research pharmacist is aware of the arm assignment. The fifth subject enrolled in the trial develops severe hepatic failure complicated by encephalopathy one month after starting the study.

The known risk profile of the new oral agent prior to this event included mild elevation of serum liver enzymes in 10% of subjects receiving the agent during previous clinical studies, but there was no other history of subjects developing clinically significant liver disease. The IRB approved protocol and informed consent document for the study identifies mild liver injury as a risk of the research.

The study sponsors determined that is an unanticipated problem that must be reported because although the risk of mild liver injury was foreseen, severe liver injury resulting in hepatic failure was unexpected in severity; possibly related to participation in the research; and serious.