HL7 RCRIM WG

FHIR AdverseEvent Resource

CALL MINUTES: Friday, June 16, 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

AGENDA:

1. Approve minutes from June 2
   http://wiki.hl7.org/images/b/b3/FHIR_AdverseEvent_Resource_Agenda_and_Minutes_2017-06-02.pdf
2. Update on FHIR AE resource sponsoring work group
3. Look at terminology bindings for AdverseEvent.event in SNOMED CT
4. Address outstanding GFORGE trackers:
   a. 13310: http://gforge.hl7.org/gf/project/fhir/tracker/?action=TrackerItemEdit&tracker_item_id=13 310&start=0
   b. 13302: http://gforge.hl7.org/gf/project/fhir/tracker/?action=TrackerItemEdit&tracker_item_id=13 302&start=0
5. Other issues – review GFORGE 13308 as per disposition
6. Next meeting pending FMG changes

Minutes

1. Minutes Approval: postponed – no quorum.
2. GFORGE Requests
   a. Began with the discussion of appropriate terminology bindings for AdverseEvent.event.
      i. Currently this element is (as a suggestion) bound to SNOMED CT Clinical Findings. This may not fit all of the use cases for this resource.
      ii. The SNOMED Event class was explored as a better binding based on use cases.
         1. Example SNOMED CT Event concepts include
            a. Accidental fall (event)– concept code 217082002
            b. Medical accidents to patients during surgical and medical care (event) – concept code 269691005
            c. Medication error (event) – 398240004
         2. SNOMED CT has limited concepts for medication errors (may need augmentation to make useful). The group discussed the best approach for adding terms for a FHIR resource – the use of the HL7 extension was determined to be the best approach.
      iii. The group agreed that AdverseEvent.event is best represented by the SNOMED CT "Event" domain and this change will be applied (see GFORGE).
   b. The issue of how to represent a near miss event was discussed.
      i. An event occurred, but there was no resulting harm. SNOMED CT does not allow the expression of such a concept, but perhaps MedDRA will allows for such an expression.
      ii. Other possibilities included:
         1. Condition with a negated code
         2. Use some form of resulting condition
            a. Boolean response
         3. Use seriousness and add some form of null
            a. Provide clarity on use of seriousness and severity as person-centric vs. event-centric concepts.
         4. Elaine will look at MedDRA for possible ways to express a near miss event

   c. **13310: http://gforge.hl7.org/gf/project/fhir/tracker/?action=TrackerItemEdit&tracker_item_id=13 310&start=0 -- not addressed yet**

d. **13302:** **http://gforge.hl7.org/gf/project/fhir/tracker/?action=TrackerItemEdit&tracker_item_id=13302&start=0**
    i. Discussed first aspect of comment e.g. AdverseEvent.actuality of AE|PAE. Group suggested change to Actual Event and Potential Event. Note added to GFORGE.
    ii. Will discuss other elements of GFORGE at next meeting.

3. Note that no updates based on GFORGE comments have been committed to the build pending the switch of the workgroup from BRR to PC.

Agenda for Next Meeting: (not clear what date this will be pending FMG action)

1. Review minutes from June 2 and 16
2. Review of action items
    a. SNOMED CT and MedDRA coding for representation of AdverseEvent.event "events" and "resulting conditions" or lack thereof.
    b. Review terminology as used by the patient safety community
3. Other issues
    a. **13310:** **http://gforge.hl7.org/gf/project/fhir/tracker/?action=TrackerItemEdit&tracker_item_id=13310&start=0**
    b. **13302:** **http://gforge.hl7.org/gf/project/fhir/tracker/?action=TrackerItemEdit&tracker_item_id=13302&start=0** (continue discussion)
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.

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