HL7 RCRIM WG

FHIR Adverse Event Resource

CALL MINUTES: **Friday, June 24, 2016**

Attendees: 11

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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

1) Approve Minutes for 6/10/2016 and 6/17/2016
2) Presentation by Dr. Mitra Rocca on her review of various FDA standards and other related projects for adverse event reporting.
3) Next meeting – Friday, July 1, 2016 at 10 AM ET.

Minutes

1) Approve minutes:
   a) 6/10/2016 Move: Mead/Rik
   b) 6/17/2106 Move: Rik/Mitra
2) Dr. Mitra Rocca Presentation: FDA on Current AE Standards.
   a) Mitra Rocca from FDA/CDER presented on current standards for Adverse Event and Patient Safety reporting.
   b) The slides from this presentation are posted on the HL7 RCRIM Project Wiki here:
      i) Presentation_DrMitraRocca_FDA_AdverseEventReporting_2016_06-24.pdf
   c) Slides include:
      i) Definitions for Adverse Event (AE) and Significant Adverse Event (SAE).
      ii) A description and screen shots of two MedWatch forms for reporting adverse events to the FDA – the 3500A (mandatory reporting) and the 3500 (voluntary reporting).
         (1) MedWatch is not used for:
            (a) Investigational study drugs.
            (b) Mandatory reporting by regulated industry for drugs, biologics, and dietary supplements.
            (c) VAERS is used for reporting vaccine information.
      iii) A review of the international group responsible for global reporting of adverse events for drugs and biologics (ICH). *Note that there is an equivalent group for Devices.*
         (1) The electronic standard used for reporting is the E2B(R2), and the electronic CTD (Common Technical Document) and uses MedRA as the coding standard.
            (a) Now piloting E2B(R3) in US, Japan and EU.
         (2) There is an implementation guide available.
      iv) ASTER (ADE Spontaneous Triggered Electronic Reports) was a project through Pfizer and Partners healthcare.
            (a) The slides include data flow diagrams and screen shots of the EMR with data capture forms.
            (b) This project was a pilot.
            (c) Additional slides on ASTER: http://wiki.siframework.org/file/view/ASTER_ONC_18July2013+Final.pdf
            (d) Duke will pilot using CDS in their EHR – note limit on the amount of data sent. The report will then be sent to the FDA gateway – with the ability to triage the report, prevent duplicates and parse.

v) SDC AE/PSE WG (Structured Data Capture Project through ONC)

(1) **Goal:**

(a) Validate, test, and pilot the S&I SDC interoperability standards that specify how electronic health records (EHRs) can capture and transmit structured data for Patient Safety Event (PSE) and Adverse Event (AE) reporting

(2) **Objectives:**

(a) Identify **Common Data Elements** (CDEs) and associated value sets, leveraging AHRQ Common Formats, that can be used for PSE and AE reporting from EHRs.

(b) Identify **structured forms/templates** that these CDEs will populate, leveraging AHRQ Common Formats and FDA Form 3500/3500A.

(c) Develop PSE and AE Reporting **end-to-end workflow** (from EHR system to AHRQ Repository and from EHR system to FDA repository).

(d) Identify 2 or more organizations to test and **pilot** the SDC Implementation Guide in a production or near production environment.

(3) Note that FDA reporting includes identifiers and that reporting to AHRQ does not.

(4) AHRQ has 11 different forms, FDA has both the 3500 and the 3500A

(a) Both were mapped to the ICSR

(i) MedWatch terms were entered into the CADSR

(ii) AHRQ terms – in USHIK repository

(5) For drugs – FDA will use NDC codes and UDI codes for devices.

(6) For biologics – NDC codes are available but there is still discussion about the suggested naming of biologics with NDC coding.

(a) It was also noted that some NDC codes may be missing for AE reporting.

(b) Incorrect or confusing naming can lead to misattribution of an AE.

(7) Goal of project is to allow a filing based on any piece of information.

(8) Once data reaches FDA, it is entered into FAERS.

(9) S&I Framework and AHRQ will each do their own pilots.

(a) AHRQ does not have standardized workflow – it is the workflow of the individual healthcare institution.

3) Next Steps:

a) Elaine and Sheila will develop a spreadsheet of the various data elements across existing standards. This will help define the core AE resource data elements as well as how to use data collected by other resources. If a current resource does not provide the needed data, this will drive change requests.

i) Note that the HL7 FHIR Adverse Event resource work does not imply a new standard for reporting, in fact FHIR data elements can be used to generate current ICSR reporting data elements in the future.

b) Elaine will ask Stella Stergiopoulos from Tufts for a copy of her slides.

Outstanding Questions

Questions and comments from the FHIR Management Group (FMG) related to FHIR Adverse Event Resource:

1) The scope should include events that happen to individual other than patients.
    a) Specifically, Practitioners and RelatedPersons
    b) Possibly also Devices (e.g. equipment damage)
2) Timeline should be updated to inclusion in DSTU 3 rather than 2.1.
    a) 2.1 would have been tight anyhow. Deadline is early July 2016 to have your resource at DSTU-level quality
3) For each of the "related resources", can you define what the nature of the relationship is?
    a) Reference by name – links
    b) Patient resource
    c) Observation resource
    d) Medication resources
    e) Immunizations
    f) Devices
4) Need to correct and update resource proposal and let Lloyd know.
    a) http://wiki.hl7.org/index.php?title=AdverseEvent_FHIR_Resource_Proposal

Other Questions

1) none

Action Items

1) Any line items that include explicit actions are highlighted in yellow above.

Next Call

Friday, July 1, 2016, 10 AM ET

Agenda for Next Call

1) Approve minutes from June 24 meeting.
2) Review spreadsheet of data elements from various sources
3) Continue to discuss scope of project
4) Next meeting – July 8, 2016