HL7 RCRIM WG

FHIR Adverse Event Resource

CALL MINUTES: **Friday, May 27, 2016**

Attendees: 7

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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 5/20/2016.
2) Continue discussion of outstanding questions from FHIR Management Group (FMG) related to FHIR Adverse Event Resource.
3) Continue review of Adverse Event (AE) data elements spreadsheet.
4) Review of available references for resource development.
5) Next meeting – Friday, June 3, 2016 at 10 AM ET.

Minutes

1) Approve minutes:
    a) 5/27/2016 Move: Mead/Rik Abstain – 1 Negative – 0 Approve – 5
2) Review of Spreadsheet
    a) Collecting data elements from various resources
    b) Commonalities vs. differences
    c) MeDRA - use of terms. Watch use of licensed terminologies.
    d) AHRQ – not balloted.
        i) Patient Safety reporting.
        ii) USHIK has data elements.
        iii) 1.2 version for common format.
        iv) Health care event reporting form and summary of incidents report and patient information form.

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) Does AdverseEvent adequately reflect use for patient safety issues – e.g. is the use of the resource clear?
    a) Event for Patient safety
        i) Incident (reaches the patient)(can be product problems, devices, or outcomes. (Mapped to MedWatch form)
            (1) Harm
            (2) No Harm
        ii) Near misses
        iii) Unsafe conditions
    b) Adverse Event
        i) Substance based or device based
            (1) Reportable
        ii) Product problems (defect)
            (1) Like a near miss or an unsafe condition
            (2) Depends on how close to the patient
    c) Some events are reportable to FDA and AHRQ.
        i) Report timing
    d) ICH (FDA, Europe and Japan and Pharma) and EMA standards are equivalent
    e) Resource will address both adverse event and patient safety data
    f) Out of scope – generalized reports on equipment. (auto parts, machinery).
2) FHIR Conformance
    a) Look at cardinalities and FHIR rules for assigning cardinalities.
    b) Look at order of data elements to confirm to current FHIR standards (w5 who, what, when, where…order)
    c) See http://hl7.org/fhir/conformance-rules.html
3) Need short labels and definitions
4) Outcome – might need a codeable concept or a reference to condition (discuss this)
    a) Do we need to address outcome?
    b) Medical history in AE reporting now (ICH). Look at MedWatch form. (Optional)
        i) Potential outcomes of event – hospitalization, death
        ii) Was the outcome serious- yes or no?
        iii) AHRQ does capture harm and certain outcomes e.g. wrong patient, wrong side
        iv) Should not be required
5) Discuss on 6/3: Need a context link Reference (Encounter|EpisodeOfCare), could use Study in the future.
6) Note that the "Study" resource does not yet exist. This may represent some new work for RCRIM/BRIDG.
7) Need to look across other resources for common syntax.
8) Look at other standards for adverse events and patient safety reporting to ensure we have met all use cases.

Action Items

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

Next Call

Friday, June 3, 2016, 10 AM ET

Agenda for Next Call

1) Approve minutes from May 27 meeting.