HL7 RCRIM WG

FHIR Adverse Event Resource

CALL MINUTES: **Friday, May 20, 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) Introductions.
2) Wiki page introduction.
3) Discussion of project and review of current Adverse Event (AE) data elements spreadsheet.
4) Meeting day and time – Change is needed to time – from Noon to 10 AM.
5) Next meeting – Friday, May 27, 2016 at 10 AM ET.

Minutes

1) Team roles reviewed.
2) Individual Case Safety Reports (ICSR) adopted for messages between pharma, device manufacturers, and regulatory agencies.
    a) Interest from providers who wish to relay adverse event messages for non-regulatory purposes.
    b) We need to understand content and the implementers who would use this resource.
    c) V3 ICSR serves as a good background document with use cases.
3) FDA
    a) Wants to make clear that current implementations and use of the ICSR standard are underway.
    b) Does not want the community who must provide regulatory reporting to the FDA to be confused by work on this new resource.
    c) Note that this is a nascent project and at present will only be a draft resource – not part of the current slate of FHIR Resources that will move to a normative state.
4) AHRQ has addressed the reporting of patient safety issues.
    a) What is the difference between Adverse Event and Patient Safety reporting?
        i) AE – adverse event - needs patient specific PII.
        ii) PS – patient safety - de-identified for common format.
    b) These two standards need harmonization.
        i) For AE, sometimes reports are submitted on the same subjects, and identifiers are critical for differentiation.
        ii) For ONC – had two work streams with the resulting terms entered into the Cancer Data Standards Repository (NCI) (caDSR).
    c) A reportable condition for AHRQ may be more broad.
5) Old patient safety Workgroup had requirements for both.
    a) There is an old data model – there is an CDA implementation guide. - Mead will look for these.
    b) May include hospital acquired infection and falls.
    c) ICSR is associated with a product.
    d) AHRQ not associated with a product.
6) The group then began looking at the actual spreadsheet of data elements and cardinality.
    a) The related spreadsheet as of today is on the Wiki page.
7) Note the group agreed that this resource does not cover adverse event reporting per se. That would involve other aspects of FHIR.

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?
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?
2) Look at cardinalities and FHIR rules for assigning cardinalities.
    a) http://hl7.org/fhir/conformance-rules.html
        i) See 1.12.2 Cardinality
3) Look at order of data elements to conform to current FHIR standards.
4) Need short labels and definitions.
5) Outcome – might need a codeable concept or a reference to condition (discuss this).
6) Need a context link Reference (Encounter|EpisodeOfCare).
    a) Could use Study in the future.
    b) 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: New

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

Action Items: In Progress

1) None.

Next Call

Friday, May 27, 2016, 10 AM ET

Agenda for Next Call

1) Approve minutes from May 20 meeting.