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| C:\Work\HIT_proj_FHIR_AdverseEvent\Formatting\fhir-logo-www.png | **HL7 RCRIM WG**  **FHIR AdverseEvent Resource** |
| **CALL MINUTES: Friday, January 6, 2017** |

### Meet online at [www.webex.com](http://www.webex.com), meeting number: 196 412 889

### Phone +1 770-657-9270, passcode 7485962

## Attendees: ##

|  |  |  |  |
| --- | --- | --- | --- |
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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>
   1. See 1.12.2 Cardinality

## Agenda

1. Agenda – review minutes from last meeting:  <http://wiki.hl7.org/images/2/20/FHIR_AdverseEvent_Resource_Agenda_and_Minutes_2016_12_09.docx>
2. Finalize use cases
3. Review list of data elements for the AE resource
4. Planning for San Antonio WG meeting – Wednesday Q3

## Minutes

1. Approve minutes:
   1. December 9, 2016 Move: Mead/Rik
2. The group agreed that there are adequate use cases at this point.
3. The group then moved to the review of the proposed data elements for the FHIR AE resource.
   1. Adverse Event Type – the discussion centered around how to adequately describe the variety of events that may be covered by this resource. It is clear that an actual event, such as an adverse event related to a study, or an actual patient safety event such as slip or fall could be adequately described using the current constructs and MeDRA terminology coding. However, it may not be clear just from a code for searching purposes what type of event occurred. The group then decided to add a category concept to provide better searching capability. This is designed to provide some degree of classification of the event if know and allow for such concepts as a “near miss”.
      1. Note that in Canada there is a concept of degree of severity of near miss – mild, moderate or severe.
   2. The issue of a medical order was discussed. It was determined that could reference the order concept especially when describing the event.
   3. The issue of how to describe a product problem was discussed. This may or may not be subject agnostic but needs to be represented.
   4. The group then discussed the relationship of an adverse reaction, the Allergy and Intolerance resource and the relationship to the Adverse Event resource.
      1. The AE subgroup has endorsed the use of a separate adverse reaction resource that can be referenced by both the AI resource as well as the AE resource. However, remaining questions linger about the larger context of FHIR and the potential use of Condition or Observation. It is also not clear how to represent causality.
   5. The group agreed that the AE resource should reference “Research Study” and “Detected Issue” but has not yet described these relationships fully.
   6. The group discussed elements around reporting – this requires further discussion on how to best do this in FHIR.
   7. The group reiterated the need to link to Medical History – this needs further discussion.
4. Use Case list
5. Adverse Event
   1. Drug\*
   2. Biologic
   3. Device\*
   4. Vaccine
   5. Medical Food\*
   6. Dietary Supplement\*
   7. Herbals
   8. Food
   9. Cosmetics
   10. Reporter variations
       1. Healthcare Reported
       2. Patient Reported
       3. Manufacturer Reported
       4. Veterinary Reported
       5. Supply Chain
6. Medication Reconciliation\*
7. Product Problem (device)\*
8. Product Quality (office of pharmaceutical quality)
9. Product Use Error
   1. Wrong dose\*
   2. Package insert error\*
   3. Wrong technique\*
   4. Wrong route of administration\*
   5. Wrong rate\*
   6. Wrong duration\*
   7. Wrong time\*
   8. Expired drug\*
10. Problem with use of Medication from Different Manufacturers
11. Protocol Adverse Event with IND
    1. Serious Adverse Event
    2. Unanticipated Problem\* (Consider international terminology)
12. Patient Safety Incident\*
13. Patient Safety Near Miss\*
14. Patient Safety Unsafe Condition\*

## <http://hl7-fhir.github.io/event.html>

## Outstanding Questions from FMG

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

1. The scope should include events that happen to individual other than patients.
   1. Specifically, Practitioners and RelatedPersons
   2. Possibly also Devices (e.g. equipment damage)
2. For each of the "related resources", can you define what the nature of the relationship is?
   1. Reference by name – links
   2. Patient resource
   3. Observation resource
   4. Medication resources
   5. Immunizations
   6. Devices
3. Need to correct and update resource proposal and let Lloyd know.
   1. <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.
2. Begin writing resource text in the format used for other FHIR Resources. Example: <http://hl7.org/fhir/allergyintolerance.html>

## Next Call

The next meeting will be at the San Antonio WG meeting – Wednesday, January 18, Q3