HL7 RCRIM WG

FHIR Adverse Event Resource

CALL MINUTES: **Friday, June 17, 2016**

Attendees: 10

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X	Pooja Babrah		Point of Care Partners
X	Rashad Hasan		FDA
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X	Stella Stergiopoulos		Tufts CSDD
X	Susan Terrillion (AHRQ/CQuIPS) (CTR)	Susan.Terrillion@AHRQ.hhs.gov	AHRQ
X	Thomas Felix		AMGEN
	Wayne Kubick		CTO HL7
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	William Gregory (NYC)	William.Gregory@pfizer.com	Pfizer

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 - deferred.
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) Presentation of the Adverse Event Survey Study by Tufts University by Dr. Stella Stergiopoulos.
5) Presentation Pooja Babbrah – Point of Care Partners
6) Review of other AE and patient safety documents that can be used for input and clarification of resource requirements.
7) Next meeting – Friday, June 24, 2016 at 10 AM ET.

Minutes

1) **Dr. Stella Stergiopoulos and Dr. Kenneth Getz – Tufts Center for the Study of Drug Development (CSDD), Adverse Event Study Survey**
    a) Information to help drugs, regulators for review and utilization for drug development.
    b) Pharmacovigilance and signal detection is key activity for this group at Tufts.
    c) Study initiative – in process of being reviewed for publication in Journal of Drug Safety.
    d) In 2013, completeness of MedWatch data – essential data was not consistently reported.
    e) What is the role of HIT in pharmacovigilance?
        i) Should not be a barrier to reporting ADE.
        ii) Should link patient care, pharmacy, and institutional safety systems.
        iii) Should comply with government policies and standards – patient, event, drug, and reporter.
            (1) At drug level – need the name, link to manufacturer, batch in database.
            (2) Should be able to link to other meds patient is on.
    f) How is Health IT doing?
        i) Phase I – Interviewed 11 experts – mapped ADE reporting process flows and HIT systems in various care settings.
        ii) Phase 2 – Survey – 87 responses.
    g) Findings: Survey findings identified in a typical hospital.
        i) Reported internally to FDA and to the manufacturer.
        ii) Seven electronic systems in play in a hospital setting – EHR, CPOE, eMAR, barcode, barcode in pharmacy, incident reporting system, billing systems.
        iii) How are these integrated? Really there is no integration.
        iv) Does lack of integration between systems – 52% -- a barrier to reporting?
        v) Can't pinpoint drug, nor how to report.
        vi) Each system captures different things.
        vii) Incident reporting system not integrated with other systems – hard to push data forward to FDA or manufacture.
        viii) Unclear who is responsible for data entry and reporting.
        ix) Data are also captured on paper.
        x) Drug info not available – dose, route of administration.
        xi) Lacking NDC, manufacturer, exp date, lot number – key for reporting **Biologics.**

h) HIT is key – but lack integration and key information.
i) Recommendations – integrate, add missing elements.
j) Limitations – 3 US states: NY, NJ, Washington.
k) Questions were specific to standard patient care, not research.
l) Next questions – also an educational gap for health care providers and reporting.
m) Data warehousing – where will integration happen??
    i) Often data warehouses are not available or this group was not aware of these options.
    ii) These data are from hospitals, not retail pharmacies or private practice.
n) Private practice – barriers were similar. Patient does not report the ADE to the pharmacist.
o) In hospital setting there is more clarity – other settings not clear how to report.
p) Databases – OPTUM or Sentinel – specific AE may not be included in these systems.
q) Quantros – does keep a database that might be available for signal detection for adverse events.

2) **Pooja Babbrah – Point of Care Partners**
    a) Looking at Health IT systems side – what is in the EHR and the Pharmacy system for reporting?
    b) Spoke with EHR system vendors and pharmacy system vendors – data at point of prescribing as well as administration.
        i) Administration data may not flow back into the EHR.
        ii) What standards will help with this gap and what is the key information?
        iii) Patient provided information?
3) **Susan Terrillion** – AHRQ – has 70 some systems.
4) **National Patient Safety Foundation** – Thomas Felix will provide contact.
5) MedWatcher.org – Epidemico – private company funded by device group at FDA – helps with reporting. Takes four common elements.
6) HealthMap.org – outbreaks.

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) What is the role of HIT in pharmacovigilance?
2) National Patient Safety Foundation – **Thomas Felix** will provide contact.
3) Any line items that include explicit actions are highlighted in yellow above.

Next Call

Friday, June 24, 2016, 10 AM ET

Agenda for Next Call

1) Approve minutes from June 17 meeting.
2) Presentation by Dr. Mitra Rocca – FDA on current AE standards.