2020-01-16 Patient Care FHIR Conference Call

Meeting Information

Phone Number: +1 563-999-2090
Participant Passcode: 792564

WebEx: https://join.freeconferencecall.com/patientcare
Chair: Michelle Miller
Scribe: Michelle Miller

Attendance

Attendee	Name	Affiliation
X	Stephen Chu	The Australian Digital Health Agency (ADHA)
	Irina Connelly	Georgia Tech Research Institute
X	George Dixon	Allscripts
	Evelyn Gallego	EMI Advisors LLC
	Eric Haas	Health eData Inc
X	Rob Hausam	Hausam Consulting LLC
	Laura Heermann-Langford	Intermountain Healthcare
	Yanyan Hu	Joint Commission
	Emma Jones	Allscripts
X	Thom Kuhn	
X	Russ Leftwich	InterSystems
X	Tony Little	Optum 360
X	Jay Lyle	Ockham Information Services LLC, VA
X	Chris Melo	Philips
X	Michelle M Miller	Cerner
	Lisa Nelson	Max MD
X	Mike Padula	The Children's Hospital of Philadelphia
	Joe Quinn	Optum
	Nick Radov	United Healthcare
	Stefan Roth	Georgia Tech Research Institute
	Casey Thompson	Clinovation
	Jack Wallace	Georgia Tech Research Institute
X	Christi Denney	
X?	Hugh Glover	

	Wayne Kubick	
	Andi Maddela	
	Amy Nordo	
	Lynn Perrine	
	Robinette Renner	
	John Stamm	
	Mead Walker	
	Barbee Whitaker	
	Tom Yosick	
X	Suranjan De	FDA
X	TJ Chen	FDA
X	Boris Brodsky	FDA

Quorum (chair + 3) met? Yes

Agenda

1. Agenda Review
2. Approve previous meeting minutes 2020-01-09 Patient Care FHIR Conference Call
    a. Motion: Stephen/Thom
3. gForge change requests

AdverseEvent

Suranjan described FDA use case:

- Different specialty pharmacies submitting 140k reports to FDA - mostly via fax (using existing MedWatch form) - voluntary (not mandated - only mandated for manufacturer)
    - demographic (patient)
    - reporter (who)
    - products (drug)
    - adverse event that occurred - **large narrative** story about the incident that occurred
- For the pharmacies that already using electronic systems to capture this information, could they submit it electronically through standard (versus time consuming form that exists today)
- Could we get a copy of de-identified data in a MedWatch form that is used today? Yes, on FDA website: https://www.fda.gov/media/76299/download (3500 PDF) - Question 5B is the narrative - look to represent sections A (patient info), B (adverse event), D (suspect product), E (suspect medical device) and G (reporter) - haven't done mapping to see how well FHIR resource aligns with those aforementioned sections
    - Section A: combination of Patient + Observation (for weight) using US Core extensions for height / weight per https://build.fhir.org/ig/HL7/US-Core-R4/profiles.html
    - Section B
        - Type of Category = AdverseEvent.category (binding strength is example, so the value set can be changed)
            - What is the meaning of AdverseEvent checkbox? Aren't they all AdverseEvents? Are near misses in scope?
            - If this is just about data collection (page 3 says "You're not certain the product caused the event"), then should we consider Questionnaire / QuestionnaireResponse instead? This aligns more with the clinical use case.
            - TO DO: Consider whether AdverseEvent boundaries should include forms specifying which types of forms - mandatory reporting forms in scope of AdverseEvent vs intake forms before it is deemed to be an AdverseEvent. Review a few forms in Europe, US, and Australia. Michelle will log JIRA as a reminder to revisit AdverseEvent boundaries with respect to forms.
            - **Feb 27** will be the next AdverseEvent (Jan 30 and Feb 13 are cancelled due to proximity to WGM).
- Which electronic systems for the pharmacies use that capture the adverse event? Specialty pharmacies - when patients call, then capture patient comments / medication error

Stephen gave an overview of a new page he created, Adverse Event and Consequences

- Discussion about whether signs and symptoms can be represented as a condition – reviewed existing boundaries that said

    This resource is not typically used to record information about subjective and objective information that might lead to the recording of a Condition resource. Such signs and symptoms are typically captured using the Observation resource; although in some cases a persistent symptom, e.g. fever, headache may be captured as a condition before a definitive diagnosis can be discerned by a clinician. By contrast, headache may be captured as an Observation when it contributes to the establishment of a meningitis Condition.

    Use the Observation resource when a symptom is resolved without long term management, tracking, or when a symptom contributes to the establishment of a condition.

Use Condition when a symptom requires long term management, tracking, or is used as a proxy for a diagnosis or problem that is not yet determined.

- For example, drug overdose isn't the condition – the condition might be respiratory arrest. The harm is whatever happens as a result of the overdose (e.g. swelling, respiratory arrest). Why do we need to document drug overdose? Could we use AdverseEvent.code or category? Russ suggests category and the binding is example, so profile can bind to a value set that includes overdose. Hugh thinks it might be too much detail to include in base resource's value set - and this is more an IG concern to represent drug overdose. Base FHIR specification's value set does include medication-mishap. Stephen will sleep on it and give it more thought, but his concern is that the use case is lost.

Adverse Event Use Cases is available to inventory additional use cases, as needed

gForge Change Requests Discussed

Patient Care FHIR Backlog

Adjourn

Adjourned at 6:28pm Eastern.

Next Meeting

Preliminary Agenda Items

1. Agenda Review
2. Approve previous meeting minutes
3. gForge change requests