FHIM Lab WG Information Modeling Project Meeting Minutes

Date/time of call: Monday, August 16th, 2010, 10:00 - 11:00 AM (EST) VANTS 1-800-767-1750 Code 84287

**Attendees:**

Anne Pollock – CDC

Andrew Regiec – DoD-MHS

Austin Kreisler - CDC

Galen Mulrooney - VA/VHA

Ira Lubin – CDC

John McKim - DOD

Kosta Makrodimitris – FDA

Maggie Wong – VA

Neelima Chennamaraja – VA

Sean Muir - VA/VHA

Steve Hufnagel – DOD

Steve Wagner - FHA, Project Management Officer

**Leadership Team**

Neelima Chennamaraja, Kosta Makrodimitris, Galen Mulrooney

**Experts**

Anne Pollock, Ira Lubin (CDC)

**Agenda for our meeting on August 13th**

Galen will present an overview of FHIMS and Lab-OO domain modeling efforts.

Austin will give us an overview of what exists in HL7 and what they have done so far to their lab models and share the latest documentations in HL7V3

Steve Hufnagel will conduct a walk-through of the HITSP lab use cases if time permits

Summary of Discussions

* Galen gave a brief overview of what this workgroup has been working on. Our objective is to scope and prioritize different areas of lab such as clinical, research lab vs. environmental lab to ensure that we align with current standards. The lab models that we are working on originated from VA that was based on HL7 V3. We asked Austin to provide guidance to the current HL7 artifacts. Our current lab order/result model was patient centric other than animal, location, product, etc. In the future, we are looking to extend our model to include other specimens in addition to patients. There are open interests expressed by several agencies to model other specimens.
* Austin explained that the Lab can be modeled to allow the recordTarget to be anything, not just patient CMET. It can be the Investigative Subject CMET or choice of Patient CMET based on public health entity models. The Lab was merged with Orders and Observations (OO) few years ago. Lab result is part of the HL7 Normative Edition that current information can be obtained from the HL7 2010 Release whereas the specimen domain is available through the HL7 2010 CMET Normative Edition. Regarding basic genomics, the results can be supported by HL7 V2.x. He also explained that their scope for Lab has been reduced to result reporting few years ago. Any lab orders specific to V3 will be placed in Composite Orders under OO. The Composite order deals with a variety of orders and clinical domains. The modeling effort is currently stalled due to lack of resources and a fully functional behavioral model in HL7V3. Austin has championed to get the requirements of clinical genomics to put into Lab, but the project was unable to take off due to lack of resources. We can utilize existing lab results to extend into clinical genomics results. The implementation guide is capable of producing V2.x and V3 lab results. The basics of genomics result reporting can be covered in the Lab Result V3 model except for some of the modeling associations specially created for clinical genomics use. The constraints in genomics are primarily focused on vocabularies, not much on structure/model change. The class code in observation is explicitly modeled in genomics but they are inherited in Lab result model. Canada is the implementer of Lab V3 and their focus is on human based clinical reporting. As long as we can identify the recordTarget associated with lab result other than a person, the specimen can literally be anything. Also, anything that can be modeled as V3 entity can be a specimen. The model can document the parent child relationships between specimens.
* Ira addressed a concern whether HL7 considers reflex testing or integration test result that is based on the outcome of a lab result. Austin explained that lab result ordering does not deal with the reflex testing but the structure of the lab result is very flexible that it takes into account multiple levels of containers used to gather things associated with reflex testing. Lab results can include any reflect testing scenarios but not reflect ordering. Also, a second test order cannot be resulted based on a primary test. From the lab order perspective, a composite order can cover lab, pharmacy, radiology, etc.
* Kosta would like to know where we can locate the materials for active projects, whether lab was extended to include genomics test, etc., or whether there are any existing cases/projects that deal with animals/inanimate objects (In the HL7 website: substances, medical devices, specimen, microbiology, blood center, OO maintenance are active). Kosta also asked if there are any projects waiting for approval. Austin explained that there are planning projects pending on resources and participation and he encouraged us to join the HL7 OO domain and projects. He mentioned that there are several other HL7 domains that overlap and collaborate actively with OO(Anatomic Pathology, Clinical Genomics, Clinical Statement, Healthcare Devices etc). Another case to discuss is the communication of Lab results (microbiology, genetic) to Electronic Health Records or other clinical system (HITSP has a relevant use case). HL7-OO hasn’t done any active work or collaboration with HER HL7 domain so far.
* Anne mentioned that lab ordering can influence result reporting where a patient gets what he or she paid for. She would like to know if the impact of not having test ordering components in an order has been validated, is there any indication that a report is incomplete and if data governance was considered. Ira also expressed the same concern that there is incomplete information on both sides where the information in an order form is not making it to the performing laboratory and/or the test result performed by a lab is not getting back to the clinician due to systems being developed in different environments. Austin explained that a lab result can be incomplete, corrected, etc. The capability is in the rules of messaging that it should be flexible so individual can apply their own policy. The universal standards should provide options for users. Also, there is no universal data governance since they are implementation specific. It is unreasonable to mandate everyone to implement the level of details in a message.
* Galen would like to know the priorities of researching the standards such as HL7 V2, V3, etc. Austin explained that V2.x is probably the place to start since it is implemented mostly in US. Lab reporting is matured since HL7 V2.x covers more than lab. He believes that the Anatomic Pathology is covered in the Specimen domain (V3).

Austin does not recommend using the IHE profiles since there are mistakes that are not corrected. CDA R2 has major short coming to handle lab result especially in specimen area. In the future, CDA R3 will be able to handle everything for Lab.

* Anne also wanted to know if specimen includes all types of tissue like hair. Austin indicated that it can be done as long as the model is rich enough.
* Kosta would like to focus on Bio-surveillance HITSP use case at next week’s meeting since it maybe relevant to national food safety system case. If time permits, we may begin to explore the specimen domain. Kosta suggested using the time on Friday’s call to discuss HL7 2010 Normative Edition.

**Agenda for our Next Meeting on August 23rd:**

* Steve Hufnagel will conduct a walk-through of the HITSP lab use cases(General Lab Orders, EHR/Lab, Lab results, Biosurveillance, Public Health Case Reporting)
* ALL: Milestones-Risks for modeling efforts and use cases of Lab-OO domain
* ALL: Invitation from Steve Wagner to extend meeting for modeling and uses cases of Lab-OO domain on Friday general FHIMS calls (60’) 2:30 to 4:30pm.
* Kosta(FDA), Anne-Ira(CDC), will focus/discuss Biosurveillance use case(as time allows)  
  HITSP: Biosurveillance is an American Health Information Community breakthrough area defined as implementation of real-time, nationwide public health event monitoring to support early detection, situational awareness, and rapid response management across public health and care delivery communities and other authorized Government agencies.