FHIMS Lab-Orders and Observation Domain Meeting Minutes (January 24th to January 28th)
Agenda for the next meeting (January 31st)

Date/time of call:
Monday, January 24h , 2011, 10-11:30 AM (EST)
Friday, January 28h , 2011, 4PM (EST)
Call: 1-800-767-1750**, Passcode:** 84287
Microsoft Office Live Meeting

Leadership team

Kosta Makrodimitris, Galen Mulrooney, Cindy Vinion
Website: https://www.projects.openhealthtools.org/sf/projects/fhims/

Attendees

Neelima Chennamaraja, VA
Mike Fitch, DoD
Kosta Makrodimitris, FDA
Galen Mulrooney, VA
Anne Pollock, CDC
Ken Salyards, SAMSHA
Cindy Vinion, NG/CDC
Steve Wagner, ONC

Agenda

- ALL-Galen: Modeling Information and decide on classes, patterns and granularity
- ALL-Kosta-Anne: International Society for Disease Surveillance cases-report(10')
- ALL-Kosta-Neelima-Cindy: Discuss use case and scenarios (10')
- ALL: Lab class definitions for the models(5')
- ALL: Milestones-Plans-Risks for modeling & use cases(3rd iteration) (5')
- ALL: S&I Lab, NHIN DIRECT lab, HL7 Lab-OO,(5')

Summary of Discussion

- 'Specimen' modeling has been completed a first phase. In the future to look deeper in HL7 specimen domain.
- The test structure (currently reflecting the VA's Vista system) needs to be completed and is the next section of the model the group will complete. We may want to use the model to lock down the optionality to ensure that nonsense is not supported by the model (e.g., someone could not have bacteriology results associated with a virology test).
    - There needs to be a balance between modeling for capturing and storing data vs modeling for exchanging data; FHIMS should support exchange.
    - Many of the rules that govern which results are appropriate for a test and/or which test is appropriate to be performed on the specimen are enforced in the LIS or LIMS. These rules may also be enforced through mapping tests (and their associated codes) to results (and their associated codes); the FHIMS model does not need to enforce these rules.
- From FDA: Kosta showed the FHIMS model (as of Dec 2010) to FDA SMEs. They feel that many lab test categories are missing including forensics, chemistry, genetics, toxicology, nanotechnology, molecular biology etc. The FDA would like to cover all lab areas and then use scenarios and use cases to figure out what data needs to be shared and how.
    - Anne stated that the CLIA regulations define different lab groups and categories for accreditation purposes. Since these categories are for accreditation purposes, they may not all need to be in the FHIMS model; however, this list is a good place to start for clinical testing. We can add others as needed when we add in environmental, food, veterinary, and other non-clinical testing.
    - The category list starts in CLIA Part 493 starting with Subpart H. See http://wwwn.cdc.gov/clia/regs/toc.aspx
    - We could use the CLIA categories to model the general scope. Here is the resource for lab types http://wwwn.cdc.gov/clia/oscar.aspx
    - Mike: these regulations govern testing for accreditation and may not need to be in the FHIMS model.
- CLIA also has anatomic categories in Part 493, Subpart K. These may be useful for pathology testing.
    - Galen: Pathology may be the easiest place to start since it is currently text-based.
- Orders for genetic testing are a bit different than orders for most testing.
- Steve: FHIMS Lab needs to figure out how to set up your phases.
    - Phase 1: complete clinical lab testing and results - to cover the HITSP Lab results to EHR guide focusing on chemical and biological testing.
    - Next phase(s): add in other clinical testing including genetics, pathology, etc; testing of environmental, food, and animal subjects; biosurveillance; research; others as identified.

Discussions following up during the week and Friday

Here is the CLIA reference at the FDA's web:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm (lab and analyte specialty-search hundreds of real cases in different categories). This is another lab reference related to food http://www.fda.gov/Food/ScienceResearch/
The other perspective is to see the observations in different 'length' scales but holistically (according to discussions with MD and epidemiologists at FDA):

- physiologic- imaging, stress, pulmonary
- anatomic-whole body, surface
- gross-organs(like autopsy)
- histology- cell tissues
- standard- chemistry/hematology/toxicology/microbiology/imaging-electron microscopy
- genetics/genomics & other molecular http://wwwn.cdc.gov/dls/genetics/default.aspx

Computer experiments is also another category of 'lab' results that can be exchanged in clinical and environmental cases.

Ira suggested that genetics shouldn't be a separate entity from the lab-oo domain:

First, it has been difficult to define what is and is not a genetic test. This is because at some level, there is a genetic component to most clinical measurements. This is also because genetics is cross-cutting that is relevant to a number of modalities such as oncology, heritable diseases, and markers for drug metabolism. Molecular genetic studies are also relevant in the infectious disease world such as in sequencing HIV for the purpose of drug selection.
Second, testing for heritable conditions is no longer confined to specialty laboratories. We are seeing these types of tests increasingly integrated into general chemistry and hematology laboratories.
Third, this trend is expected to continue with advances in sequencing technology. We believe that within the next five years, such technologies will be essentially available as "appliances" that can cost-effectively be implemented even in the most modestly funded laboratories. And finally,
Fourth, genetic tests and test results rarely stand alone and require integration with other test results that may be both biologic and environmental. Therefore, it seems to me wise to keep genetic testing within the laboratory modeling efforts that are underway. In the end, effective modeling could provide an efficiency that otherwise would be lost if separated out

Kosta agreed with Ira said(and Anne) and he suggested similarly to the lab-oo. FDA has also relevant cases(pharmacogenomics, nutrigenomics, device genetic tests, gene therapy etc) http://www.fda.gov/drugs/scienceresearch/researchareas/pharmacogenetics/default.htm. Last year that HL7(vs2) reported genetics results in EHRs http://www.medicexchange.com/EMR/hl7-version2-transmits-genomic-data-to-ehr.html. He emphasized the fourth point that Ira made about possible need for integration and interpretation of genetic tests with other results. This is not only about genetic tests but for other tests and results that need to combine and integrate to have a full report and analysis finally. It's another reason that we need in our lab-orders and observation efforts to capture a full and representative set of categories in the federal agencies. This is what HITSP and HL7 can't give us when it comes to our specific federal agencies needs although they provide good model and material to use.

Kosta supported that we need to spend 'modeling' time to generalize(expand) the lab categories for satisfying all the lab-oo agencies giving priorities to the ones we have current expertise and participation:VA-DoD-CDC-FDA. There are three use cases that we may plan in different(or simultaneously) in our iterations:

- inpatient/outpatient (HITSP, EHR) standard clinic scenario-toxicology,microbiology (VA-DoD-CDC)
- product analysis and tracing with adverse events linked to food diseases and surveillance and/or/no EHR (FDA-CDC-FERN-ICLN)
- genetics tests and integration with other tests and results and/or/no EHR(CDC-FDA)

Working in specific use cases shouldn't affect the generalization and full representation of our lab categories in our models. Perhaps heaving parallel sessions in our meetings for different cases can help us to achieve this. We should be more explicit in modeling specific exchanges and scenarios that involve public health agencies activities/exchanges in order to move beyond generic HL7,HITSP models. UML and BPMN offer tools, patterns and components that we haven't utilize further to capture more realistic (and complex) scenarios which reflect current agency needs.

Kosta proposed a better interfacing and understanding the scope of the other FHIMS domains. All these domains(formed 1-2yrs ago) is not so rigorous and we need to continuously work in their scope. The Lab-OO (similarly with HL7) need to 'interact' with Dietetics, Imaging, Orders, Allergy etc not only in 'discussions' but having actual components in information modeling and use cases that shows the boundaries and dependencies. Perhaps we should have 10'-15' in our general Fri FHIMS calls to discuss progress and actions of inter-domain efforts.

Galen supported that genetic tests are structurally different than lab tests. He agreed and clarified that the domains scopes are somewhat arbitrary and the logical affinity of data and scoping the work will guide us to define them better. It's fine to have genetics as part of the lab-oo domain.

Cindy suggested to focus more on the agency exchanges in our use cases and to gather more information:

- Are there times when one agency requests another agency test a sample?
- When do agencies share lab result data? Does it come from an agency lab directly or is it part of a larger report such as from an investigation, device report (adverse event), etc
- Is a patient who visited a clinic in one agency (DoD, for example) referred for specimen collection and testing at another agency (e.g., VA)?
- Does one agency ship specimens to another agency for long-term storage or destruction? (I have asked some CDC people this; hopefully I will get an answer soon)

Kosta agreed that we need more explicit scenarios and modeling of specific federal exchanges, He urged for agencies participation to gather material and requirements (pathologists, lab experts, teams).

Kosta supported that it's more than agencies exchanges in the scope of FHIMS/FHA According to the ONC website: *FHA is responsible for:*
-Supporting federal efforts to deploy health IT standards
-Ensuring that federal agencies can seamlessly exchange health data among themselves, with state, local and tribal governments, and with private-sector
It's not just what FDA-CDC-VA exchanges but it's more than that(same for NHIN). And the model(s) need to be general to cover EHR and meaningful use. We should respect and leverage VA efforts(our baseline) and HITSP EHR-lab, biosurveillance and other cases/models developed so far.

Steve agreed that we are supporting interoperability between Federal organizations and the organizations they interact with., so that includes state, local and private sector. We aren't interested in duplicating other efforts. If they have already modeled information for an information exchange, we want to pull that into the FHIM and only modify it if necessary. Also, since we are modeling the HITSP/AHIC Lab use case, we are certainly modeling organization-to-organization exchange of information and I believe a Lab report exchanged between a Lab and an EHR systrem is the same information that would be exchanged between two EHR systems (e.g., DoD to VA).

FRIDAY 2011-01-28

During the Friday regular meeting (30') we discussed the CLIA and other sources to expand and generalize the lab-oo categories across the agencies moving forward beyond the specific VA model baseline. Anne emphasized the CLIA should be uniform and consistent amongst the agencies(CMS,CDC, FDA). Rob, Kosta agreed on that. Kosta presented some examples and cases for CLIA and devices in the FDA web.

Then we spend some time to discuss the design of the poster accepted in AAAS 2011 annual international meeting(general session, Math, Engineering and Technology): *Federal Health Information, Modeling and Standards (FHIMS) Work Group (WG) domain: Laboratory, Orders and Observation (Lab-OO) information exchanges and Electronic Health Records (EHR). Here is possible outline for a 4'x8' size:*

- ***Title*** *(1-2 lines)*
- ***Abstract*** *(50 words) optional*
- ***Introduction*** *(FHIMS/FHA, Domains-Inter, Lab-OO)*
- ***Objectives*** *(exchanges, harmonization, electronic)*
- ***Materials and methods*** *(UML, BPMN, HITSP, HL7, EA, Terminology)*
- ***Results*** *(parts of information model, 2 use cases diagrams)*
- ***Plans*** *(categories, cases, iterations, MDHT, SAIF, S&I, NIEM)*
- ***Conclusions*** *(EHR, surveillance , public health, security-privacy, performance, meaningful use, analytics, interoperability)*
- ***Literature cited*** *(ONC/FHA, HITSP, HL7, FERN/ICLN, cases)*
- ***Acknowledgments*** *(agencies, participants-link-OHT, guests ONC/FHA)*
- ***Further information*** *(EU, Canada, ONC, POC: S.W.(pmo) , HL7)*

Kosta and Rob discussed the AAAS scope and the FHIMS strategy in this and following conferences. Kosta supported that it's great to discuss and expose models and cases in a broad international community, Getting feedback from different angles and perspectives will help in the acceptance, recognition and creating more realistic scenarios. Other conferences we may participate are the HIMSS conferences (http://www.govhealthitconference.com/) and HL7 related(International HL7 Interoperability Conference :The Tomorrowland of Health http://www.hl7.org/events/ihic2011)
Kosta and Steve gave more information about the S&I Framework - Lab Interface Initiative. Steve initiated the effort to have representation of all the domains(leadership) and to be able to create accounts as non-committed members. The website and wiki of S&I http://jira.siframework.org/secure/Dashboard.jspa allows participation and comments. Since the statement for a committed member requires active participation and a lot of time to attend and contribute to meetings, Steve (& Kosta) and all agree that is better to don't commit this time. However we'll interface and keep track the initiative(lab-oo).

Steve mentioned that we can disclose to public the material and models developed in the FHIMS Lab-OO domain so far. The authors can add the term 'contractor in a parenthesis after the name of the federal agency they work for (Galen). Kosta suggested to don't display the whole UML information model but parts of it to explain better in the audience eg(**what:**sample, patient, animal, etc.**who:**patient, public health, clinic, EHR, industry, clinic,etc. **how/why:** order, collect, test, observe, analyze, classify, store, report, etc. All agree to reference organizations-literature and acknowledge agencies and participants. Steve proposed that it maybe possible to have

Action Items

Start Date	Priority	Action Item	Status
11/22/10	Low	7) Wendy-Kosta-Galen-Cindy: Clarify Specimen-Sample filler and placer order number, test identifier, placer group number and universalServiceIdentifier. The Pathology Laboratory uses specs from DICOM (Supplement 122) to describe the various units (specimen, accession number, etc) in workflow.	In process
11/22/10	Low	8) Kosta-Steve: Services Aware Interoperability Framework and Lab-OO FHIMS relevance (Lab-OO Hl7 domain has done some work, Cindy)	In process
11/15/10	High	9)Mike, Cindy, Galen: Finalize definitions for and use of different identifiers & numbers in lab domain - filler order number, placer order number, group number, test identifier, etc.	In process
11/8/10		10) Need to discuss different scenarios involving different people (ward clerk, nurses, physicians, physician's assistants, interns, etc) and who those people would be in a data exchange.	Not started
11/8/10	Low	11)Tim (ICLN) to determine if they would like to participate in FHIMS.	In process
11/1/10	Low	12)Cindy will update sample accessioning scenarios.	In process
11/1/10	Med	13)Anne will write up lab processes to include as additional scenarios.	In process
11/1/10		14)Cindy to identify and contact FBI person from LRN National Meeting for participation in the FHIMS Lab calls when we start doing Chain of Custody, slated for phase 2.	Not started
11/1/10	Med	15) Kosta/Cindy to transform flowchart of outpatient scenario to BPMN. The first BPMN 1.2 draft is done and need to review and add data objects.	In process
10/25/10	Low	16)Keep in touch with Ted Klein and get material and links Update 11/1: Ted waiting for approval to release draft version of volume V	In process
10/25/10	Med	17)Contact laboratory experts, LIMS admins, HL7 OO WG Update 11/1: HL7 OO WG information shared with interested participants	In process
11/09/10	Med	18)Kosta to present relevant material for Automated Laboratory Management, FERN, eLEXNET . Kosta may invite some experts for Medical Countermeasures from the FDA agency and collaborating contractors.	In process
11/08/10	Low	19)Galen to update weekly the FHIMS Lab-OO model and collaborate with Kosta to update about changes from baseline(map .xls-overview)	In process (reccuring)
11/17/10	Low	20)Kosta-Galen-Cindy-Steve-Neelima to prepare and design a FHIMS-Lab-OO poster accepted for AAAS meeting in DC(Feb-20th 2011)	In process
11/17/10	Low	21)Kosta to invite CFSAN statisticians to present possible scenario for lab collaboration with CDC (sample hygiene-diseases)	In process
11/17/10	Low	22)Kosta to prepare sample use case for FDA/ORA lab automation and model in BPMN(draft completed). Present and organize library of BPMN cases.	In process
11/17/10	High	23) Kosta-Cindy-Galen-Steve: Plans and documentation of modeling efforts and cases during the next 3 meetings as the end of the 2nd iteration of the Lab-OO. Schedule and plan the 3rd iteration Jan-April 2011	In process

Completed/Not Tracked Action Items

Start Date	Priority	Action Item	Status
11/8/10		6)Tim (ICLN) to discuss with DHS the sharing of the Actionable Data Elements spreadsheets with definition.	Completed
11/1/10	Low	5) Cindy to share meeting information for the next meeting when it is sent by the co-chairs(ICLN).	Completed
11/1/10	Low	4) Cindy to send flow chart PDF to Anne Pollock	Completed
10/25/10	Low	3) Kosta-Galen will organize the OpenHealthTools shared project space for Lab-OO, Update 11/1: Steve working on organizing the OpenHealth tools project space	Completed
10/25/10	High	2) Prepare for FHA leadership meeting to present FHIMS domains process (Steve-Sean presented,Nov-2010)	Completed
10/25/10	Low	1) Initiate a dictionary of terms and definitions for Lab (Cindy, draft)	Completed
12/3/10	Low	24) Kosta updated minutes, material, HL7 2.5.1 resources, HITSP cases in OHT shared space	Completed

Agenda Next Call: January 31ST 2011

- ALL-Galen: Modeling Information and decide on classes, patterns and granularity
- ALL-Kosta-Neelima-Cindy: Discuss use case and scenarios (10')
- ALL-Kosta-Anne: International Society for Disease Surveillance cases-report(10')
- ALL-Kosta-Galen-Cindy-Neelima: AAAS 2011 poster/Feb17th (10')
- ALL: S&I Framework - Lab Interface Initiative Kickoff- Feb 1st 2-3pm(5')
- ALL: Milestones-Plans-Risks for modeling & use cases(3rd iteration) (5')
- ALL: S&I Lab, NHIN DIRECT lab, HL7 Lab-OO,(5')