FHIMS Lab-Orders and Observation Domain
Meeting Minutes (January 31st)
Agenda for the next meeting (February 7th)

Date/time of call:
Monday, January 31st, 2011, 10-11:30 AM (EST)
Friday Feb-4th 2011 (during the regular meeting)
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

Robert Crawford, VA
Neelima Chennamaraja, VA
Mike Fitch, DoD
Patty Greim, VA
Ira Lubin, CDC
Kosta Makrodimitris, FDA
Galen Mulrooney, VA
Anne Pollock, CDC
Cindy Vinion, NG/CDC
Steve Wagner, ONC

Agenda

- 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')

Summary of Discussion

Modeling

- Started looking at CLIA and started discussing how to breakdown the modeling effort and the granularity needed and desired in the model. http://wwwn.cdc.gov/clia/regs/toc.aspx
- Cindy: are "condition" and "standard" in the CLIA regulations different levels or different things?
    - Anne: The "standard" breakouts
    - Kosta: Standards and conditions in CLIA reflect the Microbiology and the respective subclasses (myco-, viro-, bacterio- etc). Similarly we should do for hematology, immunology and other categories therein including genetics in the high levels first.
    - Mike: While the PT standards, as defined by CLIA, may be different for regulation purposes, the information in the test & test result is not different and the
    - Anne:
- Kosta: Add structures to the model to reflect fully the lab cases in all participating agencies
- Ira: This group is well positioned to develop a higher-level framework model and the lower-level modeling is not needed to be done by this group. Ira feels that he can take a higher-level framework and work with experts and very detailed scenarios to develop as needed.
- Kosta: We should look at the whole business process, from ordering-analyzing, to sample collection, to result reporting. 'Orders and Observation' naming can mislead us since there are other exchange information 'points' to include in the final results for reports or store for future exchanges.
  We focused on specimen (collection-processes-test) but there are other missing that affect the results or other 'exchange' points and structures of information(in time and space). Similar to 'specimen' processes there are other lab related structures that may be included in the results or exchanges eg storage/classification, analysis/methods and reporting. We need to think deeper and holistically to cover all the possible exchange scenarios and report interfaces. Perhaps we can merge some under a super Report class(Anne suggested similarly) but we may lose some exchanges then. Experts may tell you that in order to exchange information you need (even in the high level) to clarify the method used for the results or the data management approach used to store results (now or in the future queries).
    - Anne: Has some concerns with where data is stored and what they do with it. This can impact policy.
- Galen: the lifecycle that we are talking about currently, is the lab result reports and some
- Steve: If there is a piece of information needed to either do the order or the result, then it belongs in the FHIMS model. If there is information needed to get to results or an order, but is not needed in an exchange, then it does not need to be in the FHIMS model. A lot of modeling has already been done; some have not been done very well and needs to be filled in. For most of the areas, we already explored the needed information that was gathered or collected
- Kosta suggested that Autopsy has been removed from the domain. CLIA (FDA/CDC) are a good start to represent the lab categories fully.
- Cindy proposed a Lab Report class. Many, if not all testing efforts send back a comprehensive report.
    - Galen: This is a good idea since a signed, expert report is what is returned.
    - Anne: The results from the lab are always signed and follow a chain of command (and expertise). If we focus on reporting, then the needed detailed information and the lifecycle step where the information is collected or created will fall out of the discussion.
    - Kosta: Having a report class/structure is a good start but as I mentioned above we need to think other ones involved in the lab cases and included finally in the results. We may add WHO/WHERE entities such as consumer, public health agency and unit(lab types), registries and clinical trials rep, EHR, industry so that we cover important scenarios. This sub-structure is important on how to link(interface) to a possible Report or Storage class in our model

Use Cases & Scenarios

- Kosta: Can Ira write up a couple of scenarios for genetic testing?
    - Ira can provide the scenarios and would like to work with some FDA people to develop them. There are several possible scenarios, some are complicated and some are simpler.
- Kosta: HL7 has a clinical Genomics group. He will share the material with Ira. The CG wiki is on http://wiki.hl7.org/index.php?title=CG and here is some latest news for HL7 vs 2.x
- Kosta will attempt to import the BPMN diagram for the Electronic order, lab-collected specimen outpatient scenario provided by Cindy.

- Kosta: The Sentinel system is doing active surveillance and focuses on lab results this year
  -http://www.fda.gov/Safety/FDAsSentinelInitiative/ucm2007250.htm
  -http://mini-sentinel.org/
  -http://www.fdanews.com/newsletter/article?articleId=133509&issueId=14386
  The other similar (food net) case we focus currently is FERN/ELEXNET
  http://www.fernlab.org/action.cfm
    - Anne: The sentinel networks define what needs to be reported and by who. The reporting criteria are critical and many are subjective. Some of the problems that exist with the sentinel networks are garbage in-garbage out and is it difficult to predict how the information are used.
    - Kosta is proposing a scenario describing the sentinel network and lab-EHR interfaces. Mitra(med-pharm FHIMS doamin) domain leads the informatics efforts at Sentinel/FDA.

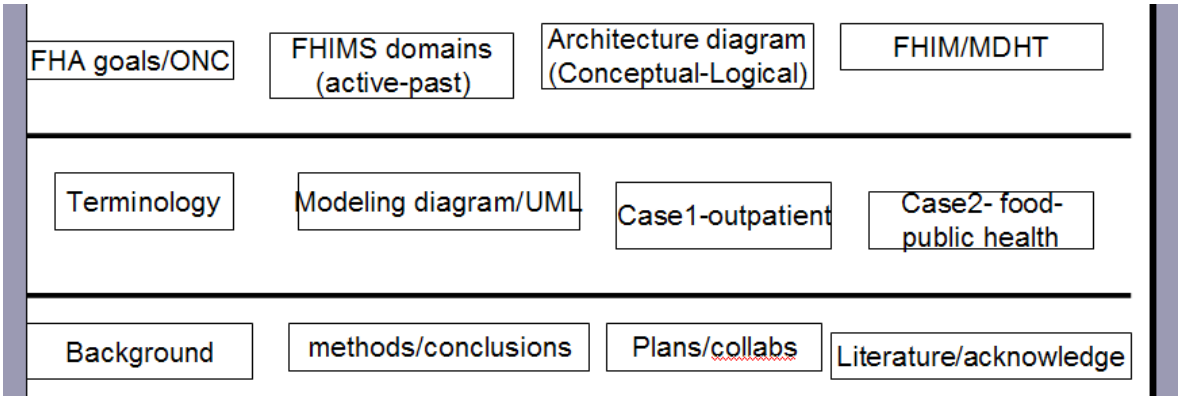
ISDS Discussion

- Anne: CDC was a consult on the report. It points out some of the issues this group is trying to deal with. Of particular interest to this group would be the process models they have developed. Please look at the some of the business processes and how they are mapped; these flowcharts should help highlight interoperability with lab reporting. It might be helpful to explore these interfaces from the lab report interfaces and to explore the advisability of and need to put the report information into a surveillance network.

AAAS Poster

- Kosta has started an outline for the poster. He shared the outline with the group on Friday.

Federal Health Information, Modeling and Standards (FHIMS) Work Group (WG) domain: Laboratory, Orders and Observation (Lab-OO) information exchanges and Electronic Health Records (EHR)



- **Title** (1-2 lines)/Authors
- **Background/History** (FHIMS/FHA, Domains-Inter, Lab-OO), **Objectives** (exchanges, harmonization, electronic)
- **Methods** (UML, BPMN, HITSP, HL7, EA, SOA, Terminology, Architecture)
- **Results** (parts of information model, 2 use cases diagrams)
- **Conclusions** (EHR, surveillance , public health, security-privacy, performance, meaningful use, analytics, interoperability)
- **Plans** (categories, cases, iterations, MDHT, SAIF, S&I, NIEM)
- **Collaboration/Interfaces** (EU, Canada, ONC, S&I, HL7,)
- **Literature cited** (ONC/FHA, HITSP, HL7, FERN/ICLN, cases)
- **Acknowledgments** (agencies, participants-link-OHT, guests ONC/FHA)

- Kosta: In the slides about cases and information model we need selectively to choose patterns and substructures that show the salient and main features. For example in the info-model: what(subject, patient, animal…) specimen processes, lab categories (chem-micro-gene-patho...), how(order, collect, observe, store, report…), entities(hospital, physician, public health, EHR etc).

- Steve: ONC has a website for publishing FHIMS output, such as the model. This website, or a similar one, will be used for additional information related to the AAAS poster. Steve will make sure that the material for FHIMS/FHA is appropriate to share.
- Galen, Cindy, Kosta, Neelima will work in different parts of the poster in order to finalize early this week since need some time to order and printout

S&I Framework - Lab Interface Initiative

We(Kosta-Cindy-Anne) attended the kickoff Lab Results Interface Initiative Launch on Tue(Kickoff Feb 1st 2-3pm ET; register at https://www3.gotomeeting.com/register/784221638)
The Lab Use Case & Requirements WG Meeting started yesterday and will be at 3:00pm EST every Thursday.
To participate and register for 'community' account go to
http://jira.siframework.org/wiki/display/SIF/Register+for+a+JIRA+Wiki+Account

- Anyone can attend the meeting.
- Kosta represents the FHIMS –LAB-OO domain in S&I Lab initiative currently and he'll share updates in a regular basis. Other domains have their own representatives.
- Steve will forward the invitation.
- Galen - This conflicts with the Allergy domain modeling meeting. Anyone who can attend, please provide an overview.

General Discussion

- Patty Greim has asked some SMEs to attend this meeting to provide expertise for the modeling of clinical pathology.

NEWS /RESOURCES

- Nationwide Health Information Network Exchange Specifications Info Session http://healthit.hhs.gov/nhin
- CLIA/CDC http://wwwn.cdc.gov/clia/regs/toc.aspx
- See http://www.stevehoberman.com/scorecard.htm for more information on the Data Model Scorecard.
- Hl7 VERSION 2.X reports genomic http://www.hl7.org/documentcenter/public/pressreleases/HL7_PRESS_20100119.pdf
- FERN presentation FDA http://www.fda.gov/ohrms/dockets/ac/03/slides/4001s1_07_Sciacchitano.ppt

Agenda Next Call: February 7th 2011

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- ALL-Kosta-Galen-Cindy-Neelima: AAAS 2011 poster/Feb17th (15')
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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