FHIMS Lab-Orders and Observation Domain
Meeting Minutes (March 14th)
Agenda for the next meeting (March 21st)

Date/time of call:
Monday, March 14th, 2011, 10-11:30 AM (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
Robert Crawford, VA
Mike Fitch, DoD
Glenn Hatfield, VA
Nikolay Lipskiy, CDC
Ira Lubin, CDC
Kosta Makrodimitris, FDA
Galen Mulrooney, VA
Anne Pollock, CDC
Anand Shukla, VA
Cindy Vinion, NG/CDC
Steve Wagner

Agenda
- ALL: FHIMS WG Cases-Processes, Metrics feedback to the general meeting (10')
- ALL: Galen: Information Modeling (classes, patterns, granularity) (30')
- ALL: Kosta-Neelima-Cindy-Ira : Discuss use case and scenarios and subgroups (10')
- ALL: Kosta-Cindy S&I LRI communication and strategies and subgroups(5')
- ALL: Milestones-Plans-Risks for modeling & use cases(3rd iteration) (5')
- ALL: Lab-OO interfaces-participation S&I Lab, NHIN Direct, HL7 Lab-OO,(5')

Summary of Discussion

Guiding principal: FHIM Lab-OO will distinguish and categorize lab tests and results, and reports based upon the data needed to:

(1) Order the test,
(2) Perform or process the test,
(3) Obtain, interpret and store data/results of the test,
(4) Report and/or release the (full/partial) results,
(5) Receive, interpret and process the report.

Actors: Hospital, Clinic, Lab types, Public Health Agency (fed-state-local), Patient, Physician, Nurse

FHIMS WG Cases-Processes-Metrics

Resource used: Modeling Process, Performance Measurements & Task Assignments documents provided by Steven Wagner after the March 10 meeting.

- Kosta - Looking for feedback from domains and/or agencies on these documents.
- Kosta - The Performance Measures seem to be internal to FHIMS. Should we add specific measurements for the active domains?
    - Steve - More domain-specific measurements would be appreciated. If you would like to see performance improvement measures (i.e., % improvement).
    - Kosta - Domains could give some overview of what has happened in the past 3 months or other timeframe as well as a vision of what is being planned for the next timeframe.
    - Cindy - What is the timeframe desired? Kosta mentioned every 3 months but the measurements seem to be yearly.
    - Steve - It is up to the group to determine if they want to share on a 90 or 120 day basis.
    - Kosta - Should this document be shared with the agencies so they can be aware and adjust their plans?
    - Steve - Sure, not problem.
    - Kosta - Lab should give some kind of a plan for the up-coming year.
    - Steve - Each domain should have a description of that they are doing for each iteration as well as what actually occurred.
    - Anne - Please clarify what is"iteration".
    - Steve - Some kind of "chunk" of effort.
    - Cindy - Is 90 days a reasonable timeframe?
    - Steve - You can span across 90 or 120 day timeframes or define a subset of tests or other information areas that is very large and break them into appropriate timeframes.
    - Kosta - Helpful to have the lab domain planned out for the next year.
- Kosta - Is the Modeling Process document complete or a draft?
    - Steve - Technically, it was finalized a while ago but, since that time, Steve has made some changes so it is draft again.
    - Kosta - Do you want feedback? Why was this document shared?
    - Steve - Cindy indicated that it would be helpful to have this document along with the other documents, so it has been provided to provide context. If there are changes needed, please share them.
    - Kosta - What is the relationship with FHA?
    - Steve - FHIMS is providing the information part of FHA.
- Steve - The Task Assignment document is based upon an FHIMS/S&I integration project work currently going on.
    - Kosta - This is a compass document for the domains.
- ***FHIMS general meeting Friday March 18th:*** *There was a general discussion from several domains on the importance of EHR functional profile (traceability, validation, organization). Need to have a plan on how to map classes and domains to EHR-S/HL7. Need expertise and alignment with agencies plans. EHR-S is still limited to cases that don't cover all public health needs. The information model(UML class) captures only structure and not behavioral diagrams that are important for use cases, S&I LRI efforts, ISDS, and transparency-robustness.*

Modeling

- Galen - VA defined "chemistry" tests as having reference ranges and abnormal flags; however, this was quickly shot down by Anne; some biological tests may also have reference ranges and abnormal flags.
    - Cindy - We also found that "chemistry" as defined by the VA did not just test for chemicals.

- o Galen - We could define "chemistry" to include some biological tests that have a similar structural construct to chemical tests.
  - o Cindy - That would just cause confusion to users of the FHIM.
- Galen - Another problem are reports that include tests that rely upon the results of another test for appropriate interpretation.
  - o Mike - You are describing a delta check where a change from previous studies is needed. Many of these are quality checks.
  - o Cindy - There are some serology tests performed on samples taken at 2 different times (acute or convalescent) that help lead to case identification. While the second test may not be performed because there isn't a second sample collection, that is immaterial for our purposes.
  - o Mike - If the lab makes the association is a local process; often it is the physician. There is a concept of delta check that is not part of a report, but is part of internal quality checks.
  - o Cindy - Would this kind of delta check be part of proficiency testing?
  - o Mike - Probably not.
- Galen - What is serology? Specifically.
  - o Mike - It usually is looking for antibodies to the pathogen in serum. Looking for a response that the body has to a particular pathogen.
- Galen - What is endocrinology?
  - o Mike - A sub-specialty dealing with hormones.
  - o They can generally be called "chemistry".
- Cindy - The subclass structure from CLIA and the VA system may not be maintained in the final logical model. Cindy suggests filling out the attributes of subclasses of the test categories from CLIA & other sources, identifying commonalities, and creating the logical lab domain model from the commonalities. This may, in the end, mean that there will be a common test object and multiple test results object each with a different structure such as one with a numeric result and one with a textual result.
  - o Mike - Any/all results can have a textual comment or remarks which can exist
  - o Galen - Only biological tests could and would have a anti-biotic sensitivity however, virology tests may have sensitivity tests
  - o Cindy - Is that appropriate for this logical modeling or is it more useful to explore those rules at a use case or example perspective?
  - o Cindy - Another thing to consider is that we are not just dealing with people; we are also dealing with environmental, animal, food, and other subjects. Sensitivity tests may be used to determine what will "kill"
  - o Mike - That is a valid point. Also, a sensitivity test may be performed to help identify the pathogen. In that case, the sensitivity may not be reported out, but the fact that it was performed may be part of the report.
  - o Mike - Some tests, including smear tests, may be performed to rule out certain pathogens.

General Discussion
- Kosta - Lab has started a few subgroups - genetics headed by Ira, cancer registries/pathology by Sandy Jones, & food testing/FERN by Kosta.
  - o Galen - How do you see the subgroups working? Will they be creating their part of the model or what?
  - o Kosta - The subgroups will be work independently and bring their results to the larger group.
  - o Galen - Sounds fine, but will they be creating a model?
  - o Ira - Genetics will need some help, but there has been some previous work done through AHIC. Some CDC people worked with AHIC; that work was a bit different than what is needed here but is applicable. The subgroup has already made contact with appropriate people in the CDC.
  - o Galen - We have not addressed the original question about what the subgroups results will be.
  - o Kosta - We still need to figure this out from an overall perspective.
  - o Galen - Will there be multiple modelers or not.
  - o Cindy - To Ira, will genetics be producing a model or wanting to update the FHIMS Lab model?
  - o Ira - Not sure yet.
  - o Kosta - They should be producing

- o Galen - FHIMS has a modeling style guide but it may not be suitable for new modelers. For example, there are data structures buried within information attributes such as address (which as an internal structure). Some tradeoffs are also made when modeling; these should be made consistently. May want to update the style guide to include some of these style decisions and tradeoffs. We may need to step back and develop more rigorous style guides and other documentation so that multiple people can work on the model.
- Nikolay - CDC is working on laboratory electronic data exchange for public health use cases and a data flow diagram. How can these efforts share information?
  - o Anne - This would be helpful because it is the use cases that are important.
  - o Nikolay - One of the foci of this effort is emergency response. Nikolay suggests having a public health focus or sub-domain for public health.
  - o Cindy - Would having an emergency response be a better sub-domain since emergency response involves more than just public health?
  - o Anne - Emergency response should utilize the same procedures but do it in a much more urgent manner.

RESOURCES
- *http://www.medscape.com/viewarticle/732504 Electronic Pathology System May Improve Accuracy and Efficiency*
- *http://pathology.emory.edu/AdminFacultyMember.cfm?Name_seq=123 Dr. Varma*
- *http://aspe.hhs.gov/sp/reports/2010/erpreqlim/report.shtml#_Toc259701197 Electronic Reporting in Pathology*
- *Provisional RecommendationCore Business Processes and EHR Requirements for Syndromic Surveillance http://www.syndromic.org/uploads/files/ISDSRecommendation-PROVISIONAL_vFINAL.pdf*
- *http://www.hl7.org/ehr/ EHR-S functional profile*
- S&I LRI UCR Structured Data Sub-Workgroup page and read the definition and material posted
- http://wwwn.cdc.gov/clia/regs/toc.aspx All of the laboratories (CLIA subcategories) we have listed must meet the requirements specified in: Sec. 493.1230 through 493.1256, Sec. 493.1261, and Sec. Sec. 493.1281 through 493.1299(test request/report CLIA)

Agenda Next Call: March 21st 2011

- Dr. Vijay Varma director of Anatomic Pathology (Lab Med, Informatics) at VA-Atlanta (electronic pathology systems),15'
- ALL-FHIMS WG Cases-Processes, Metrics review of discussions and document given to Steve,5'
- ALL-Kosta-Neelima-Cindy-Ira : Discuss use case/ scenarios and subgroups,5'
- ALL-Kosta-Cindy S&I LRI communication and strategies and subgroups,5'
- ALL: Milestones-Plans-Risks for modeling & use cases(3rd-4TH iteration), 5'
- ALL-Galen: Information Modeling (classes, patterns, granularity),30'
- ALL: Lab-OO interfaces-participation S&I Lab, NHIN Direct, HIMSS HL7 Lab-OO,2'

Action Items

Start Date	Priority	Action Item	Status
11/22/10	Low	7) Wendy-Kosta-Galen-Cindy: Clarify Specimen-Sample filler and placer order nr, test identifier, placer group number and universalServiceIdentifier. The Pathology Lab uses specs from DICOM (Supplement 122, specimen, accession number, etc) in workflow.	In process
11/22/10	Low	8) Kosta-Steve Hufnagel: 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 - filler order number, placer order number, group number, test identifier, etc.	In process
11/8/10	Med	10) Need to discuss different scenarios involving different people (ward clerk, nurses, physicians, physician's assistants, interns, etc) and people 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	Low	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, 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) Cindy- 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, Sentinel and Medical Countermeasures (FDA/contractors/partners)	In process
11/08/10	Med	19) Galen to update weekly the FHIMS Lab-OO html model and collaborate with Kosta to update about changes from baseline(map .xls-overview)	In process (reccuring)
11/17/10	Low	21) Kosta to invite CFSAN statisticians, lab experts 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). Organize library of BPMN cases, EHR functional mapping	In process
03/4/11	High	28) ALL Business cases diagrams, EHR functional model mapping, robustness model and data exchange elements to standardize	In process
03/18/2011	**High**	29) Dr. Varma introduced by W.Scharber communicated with Lab-FHIMS to join the domain and learn more about the modeling efforts at ONC/FHA	In process

Completed/Not Tracked Action Items

Start Date	Priority	Action Item	Status
11/8/10	Low	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
11/17/10	Low	20) Kosta-Galen-Cindy-Steve-Neelima to prepare and design AND PRESENT a FHIMS-Lab-OO poster accepted for AAAS meeting in DC(Feb-20th 2011)	Completed
2/28/11		25) Kosta - Develop definitions for structured and unstructured data (S& LRI WG)	Completed
3/7/11		26) Nikolay - Share ISDS Syndromic Surveillance Implementation Guide with Lab	Completed
2/28/11	High	27) Develop overview and plan for Lab domain using the Report of 2010 document. Deliver to Steve 3/18/11	Completed
03/4/11	High	24) Kosta-Galen Create space for 6 sub-WG under Lab domain(HITSP-EHR, FERN, Sentinel, cancer-pathology, genetics, lab report exchangeces)	Completed
11/17/10	High	23) Kosta-Cindy-Galen-Steve: Plans and documentation of modeling and cases during the last 3 meetings the 2nd iteration. Schedule the 3rd iteration Jan-April 2011	Completed