FHIMS Lab Domain:
Order, Perform, Observe, Interpret, Store, Report, Receive
Meeting Minutes (May 9th)
Agenda for the next meeting (May 23rd)

Date/time of call:
Monday, May 9th 2011, 10-11:30 AM (EST)
Call: 1-800-767-1750**, Passcode:** 84287
Microsoft Office Live Meeting

Leadership team

Neelima Chennamaraja, 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
Ira Lubin, CDC
Galen Mulrooney, VA
Glenn Hatfield, VA
Anne Pollock, CDC
Anand Shukla, VA
Cindy Vinion, NG/CDC
Steve Wagner, ONC

Agenda

- ALL: Finishing 3rd iteration (reports, EHR, C36/C37, CLIA) 20'
- ALL: Milestones-Plans-Risks for modeling & cases (4th iteration), 5'
- ALL-Ira: genetics use case, breast cancer 15'
- ALL-Kosta S&I LRI communication and subgroups, Terminology 5'
- ALL-Galen: Information Modeling (pathology) 15'
- ALL-FHIMS WG Cases, Style, Maps (HL7, HITSP, LOINC), Metrics

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

Summary of Discussion

Finishing 3rd Iteration

- Anne is almost finished with her summary of CLIA for the 3rd iteration report and will be sending that to Kosta later this week. Anne has sent a CLIA report and we'll review in our meetings and use as guide for the next iteration. (3RD Iteration report draft uploaded in OHT)

Milestones, Plans, Risks

- Galen & Neelima working together on reviewing HITSP C37 and ensuring that all information is accounted for in the Lab Domain model.
- Ira - CLIA provides some minimum standards and requirements but so do other entities; these entities are recognized by (CMS) as accreditation bodies of labs. The College of American Pathology (CAP), COLA and some "deemed" states such as NY and WA who accredit labs. As our models mature, we should include other entities that provide these guidelines and frameworks in our modeling efforts. CLIA is a great place to start but we need to be cognizant of other requirements and include them in the model. There are some crosswalks that have been done; Anne and Ira will attempt to locate these crosswalks and share them with the team.
    - CLIA, and the other accreditation bodies, contain requirements, including information needed for lab orders and reports of lab results. CAP, COLA, NY, and/or WA may have additional information requirements that will need to be included in the FHIM Lab model.

Modeling

- FHIM Lab, other than anatomic pathology, does not have a report per say. In the model, that object points to and uses the Clinical Document area of the FHIM. Currently, the FHIM does not include a notion of a lab report; we need to investigate if it should.
    - Galen - We have a Lab Test Referral, but it has not been thought through completely & need to be revisited and completed.
    - Galen - Some of the information called out by HITSP C36 &, therefore, part of meaningful use, include the performing lab, its address, and medical director.
- Lab reporting can happen multiple times during the whole laboratory process flow. This includes preliminary, final, corrected, and amended reports (as high-lighted by CLIA). In addition, performed lab test results that are part of an over-arching requested and promised lab test may be reported while additional performed tests within that promise are in process.
    - Anne – Every single laboratory needs to generate a report. Laboratory medical director verifies the test report results to ensure that the result reported is accurate and signs the report.
- Mike - there is a notion to optionally performed tests in a panel (see CBC).
- Galen - A lot of these complexities could be highlighted and explored if FHIM Lab had use cases. We need an inventory of use cases.
- Neelima - What is the major difference between a report and a result?

Required/Optional Performed Lab Tests

Required performed lab tests within the confines of the requested lab test (which may be a panel or a battery) and following the guidelines & the procedures the provider and lab are following, are always resulted even if the test could not be performed such as specimen quantity not sufficient (QNS). However, optional performed lab tests, if not performed, are not resulted and not reported to the provider as part of the lab report. If performed, optional performed lab tests may be resulted and reported depending up on the lab policies and procedures and expertise of the lab technicians and irectors.

Reflex testing

Lab policies and procedures as well as the expertise of the lab technicians and directors govern reflex testing and reporting of reflex test results. This is supported by the separation of the Performed Lab Test object from the Requested Lab Test. In essence, reflex testing is a lab-ordered test.

Having a lab-ordered test covers a lot of use cases such as reflex testing, reference lab referrals, accreditation & regulatory purposes, sending for testing to another lab.

Functional Requirements (for an Order Management System):

1. Splitting Orders into multiple promised/performed tests which may be promised & performed at different labs. The splitting of orders may be driven by provider/hospital and lab procedures as well as.
2. Consolidating Orders taking multiple provider requests including specimen collection (via patient interaction) and combining them into one specimen collection and promised lab test which are performed once and shared with the multiple providers. Is this the place where this consolidation happens or is it somewhere else, including multiple possible places?
    - Specific requirements and user interaction with any/all systems may be dependent upon the training and/or status of the user (aka provider). It is up to the system to be able to handle these user requirements; however, we may want to present best and good practices.

Related lab tests will need to be included in the FHIM Lab model; possibly, in many places including related lab orders, related lab promises, related performed lab tests.

S&I LRI Communications/Updates

- Approve the LRI use case & are continuing with other subgroups - Architecture, Clinical Information Model & Terminology, &. One of the subgroups (believe CIM & Terminology) is requesting information models, such as FHIM.
    - Steve will be attending an S&I LRI call today to determine which subgroup wants/needs the FHIM and will let us know what the outcome is.
- Kosta coleads S&I LRI efforts in Public Health (scope cases, with Anna Orlova, Nikolay Lipskiy) http://wiki.siframework.org/LRI+Public+Health+Lab+Results+WG
- F2F meeting in June 14th 15th http://wiki.siframework.org/June+F2F+Meeting+Registration

Genetics Use Case

Ira has lead an effort with other geneticists to write a genetic testing use case. He started with and has presented a breast cancer testing user story and listed some data elements.

- Ira will develop a flow chart of the breast cancer user story and share it with the group. Neither Ira nor Anne will be on the call May 16th; we can discuss this flow on May 23rd.

Terminology

- Kosta – participates in the FHIMS Terminology efforts. Next terminology meetings will focus on labs after finishing Allergy and Person.

RESOURCES

- *EHR-S functional profile http://www.hl7.org/ehr/*
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ANNOUNCEMENTS

- Public Health Informatics conference this summer in Atlanta: Engaging, Empowering, Evolving…Together Aug 2011 http://www.cdc.gov/phiconference/index.html
- LOINC meeting in June-6th http://loinc.org/meetings
- New forum on FHIMS OHT FHIMS concepts & maps (Describe, visualize, relate, map, trace FHIMS WG related concepts and dimensions) that will integrate with terminology/definitions/glossary documents

Agenda Next Call: May 23rd 2011

- ALL-HL7 May 2011 meeting-ballot-updates 5'
- ALL-Galen-Anne: Finishing 3rd iteration (reports, C36/C37, CLIA) 20'
- ALL-S.Hufnagel: HITSP C32/C36 and C80/C83 & EHR-FM XML standards 15'
- ALL-Ira: genetics use case, breast cancer 15'
- ALL-Kosta-Steve Terminology Lab 5'
- ALL: Milestones-Plans-Risks for modeling & cases (4th iteration), 5'
- ALL-Kosta S&I LRI communication and subgroups, 5'
- ALL-Galen: Information Modeling (pathology) 15'
- ALL-FHIMS WG Cases, Style, Maps (HL7, HITSP, LOINC), Metrics, 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 HI7 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	Low	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 business case for FDA/ORA ALM lab automation and model (draft). 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
03/25/2011	**High**	30) Maps to our classes, domains, agencies(strategy, framework, spreadsheets)	In process
03/25/2011	**High**	31) Galen will send email to Vijay-Mike to research isUrineScreenPositive" and "sputumScreenResult" attributes	In process
04/04/2011	**High**	32) Galen-Neelima evaluate and report on HL7 2.X c36, c37 coverage so far	In process
04/04/2011	**High**	33)Kosta reports on FHIM-EHR mapping and coverage	In process
04/04/2011	**High**	34) Anne reports on CLIA conformance	In process
04/04/2011	**High**	35) Cindy-Anne prepares definitions and document on ambiguous terms (ELR, EHR)	In process
04-14-2011	**High**	37) Cindy-Kosta-Galen- prepare presentation for PHI-CDC conference in August	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
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 exchanges)	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
04-14-2011	**High**	36) Cindy-Kosta-Galen-Nikolay prepare abstract for PHI-CDC conference in August	Completed