FHIMS Lab Domain:
Order, Perform, Observe, Interpret, Store, Report, Receive
Meeting Minutes (March 28ST)
Agenda for the next meeting (April 4th)

Date/time of call:
Monday, March 28ST, 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, Neelima Chennamaraja
Website: https://www.projects.openhealthtools.org/sf/projects/fhims/

Attendees

Neelima Chennamaraja, VA
Mike Fitch, DoD
Glenn Hatfield,
Galen Mulrooney, VA
Anne Pollock, CDC
Vijay Varma, Atlanta VA Medical Center
Cindy Vinion, NG/CDC
Steve Wagner, ONC

Agenda

- ALL-Galen: Information Modeling (classes, patterns, granularity),30'-45'
- ALL-FHIMS WG Cases-Processes, Maps, Metrics,15'
- ALL-Kosta-Cindy S&I LRI communication and strategies and subgroups,5'
- ALL-Kosta-Neelima-Cindy-Ira : Discuss use case/ scenarios and subgroups,5'
- ALL: Milestones-Plans-Risks for modeling & use cases(3rd-4TH iteration), 5'
- ALL: Lab-OO interfaces-participation S&I Lab, NHIN Direct, HIMSS HL7 Lab-OO,2'

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

- Vijay – Within the field of Morphology there are multiple independent variables: intracellular, extracellular, gram positive or negative etc.
- Galen: How one arrives at the result is out of scope, we can still define what a well formed report should have irrespective of any lab sub disciplines? Model contains the possibilities.
- Anne - Structured data in an order is defined by CLIA. The tests performed in every lab is the same but the process used to perform the test, are defined by the lab capabilities as well as lab policies and procedures. Because of this, we should ensure that workflow is not in the model.
    - Mike - In order to get complete clinical testing, a provider may need to fill in any missing tests by creating a separate order sent to another lab.
    - Vijay - For pathology and other testing areas, a "simple" test may be ordered but the lab is required to provide a lot of information that is very diagnostic and used in lab result interpretation and/or by the provider to provide a comprehensive diagnosis.
- Anne - When a test is performed, each lab has performance criteria for the test that the lab needs to meet. CLIA defines what must be included in the test ordered and the test report. Suggested to take a look at Subpart K section 493.1291 Standard: Test Report
- Vijay - The lab report is a good place to find variables; but, we must remember that a lot of these variables are used by other groups, such as public health, analytical or statistical metrics, or research purposes. Free-text data is not easily searched or used for these purposes.
- Anne - Each report is a snapshot in time. Each test may be performed multiple times at different times during the testing process.
- Mike - Not everything needed or known about the performed test is on the report to the provider.
- Anne - May want to use CLIA's subpart K, the quality system area, to help determine what attributes are needed for lab reports; some of the quality assurance information is needed.
- Galen - maybe we should switch to modeling the report.
    - Anne - CLIA section 1291 contains what is in the report. We could use that section to help determine what should be in the lab report model. A critical piece of information is the acceptability of the specimen for testing.
    - What is “SterilityControlResult” and is it needed for lab reporting?
- Ann- Sterility control is used to indicate the sterility for the culture media
- Mike – It was old procedure, and no one uses it any more
- Cindy - Do quality control results, such as sterility control, need to be shared electronically with groups that are not using an EHR such as CLIA or other accrediting authorities either during initial credentialing or proficiency testing?
    - Anne - Yes, there may need to be electronic reports flowing from the accredited or accrediting lab and it accrediting authority. Currently, however, these electronic reports are not the same.
- Galen - Will add a note in the diagram indicating that “SterilityControlResult” class will be revisited for accredited type of use case and this class will be deleted for now. Discussed some more quality control classes and based on the discussion “sterilityControl” flag

attribute in BacteriologyTest class is also deleted. “LabQA” class in VistA is defined only for pathology and autopsy.
    - Mike – QACode is used when pathologist comes up with an interesting case, and would like a peer review or would like someone else to look at it later. It is not part of EHR Report and QACode is not exactly used for quality assurance.
    - Galen - Based on the discussion “LabQA” class is also deleted
- Mike - Quality Control in general is tabled for this iteration
- Anne - A specimen may be processed in the lab and, during the process, become a specimen suitable for and tested by other testing procedures. For example, a tissue sample may become a frozen block for cytology.
- Anne - Any clinical observations and information about the specimen or test required or needed to help with test result interpretation may be information sent as part of the order. This is also in CLIA. CLIA is very generic which would help us build a good, generic logical model, which is where the FHIM should be.
- Galen – what is the purpose of “isUrineScreenPositive” and “sputumScreenResult” attributes in VistA under BacteriologyTest?
    - Action Item: Galen will send email to Vijay and Cc Mike to research on “isUrineScreenPositive” and “sputumScreenResult” attributes
    - “BacteriologyResult” and “ParasitologyResult” classes have been deleted.

RESOURCES

- *EHR-S functional profile* *http://www.hl7.org/ehr/*
- 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)
- CDC ELR MU http://www.cdc.gov/osels/phitpo/mu/elr.html
- http://www.cdph.ca.gov/data/informatics/Pages/MeaningfulUseRequirements-ElectronicLaboratoryReporting.aspx
- HL7 2.5.1 Implementation Guide: Clinical Genomics; fully LOINC-Qualified Cytogenetic Model, Release 1 - US Realm (1st Comment Only Ballot) – Project Insight ID: 663 *http://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm?action=edit&ProjectNumber=663*
- EHR-System Public Health Functional Profile, Release 1 – US Realm (1st Informative Ballot) – Project Insight ID: 704 *http://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm?action=edit&ProjectNumber=704*
- HL7 Version 2.6 Implementation Guide: Blood Bank Donation Services, Release 1 – US Realm (1st Informative Ballot) – Project Insight ID: 521 *http://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm?action=edit&ProjectNumber=521*
- HL7 Implementation Guide for CDA Release 2: Genetic Testing Reports, Release 1 (1st DSTU Ballot) – Project Insight ID: 460 http://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm?action=edit&ProjectNumber=460
- HL7 EHR-System Functional Model, Release 2 (1st Comment Only Ballot) – Project Insight ID: 551 Unique Ballot ID: EHRS_FM_R2_O1_2011MAY

Agenda Next Call: April 4th 2011

- ALL-FHIMS WG Cases,Style, Maps (HL7,HITSP,CLIA,EHR,LOINC), Metrics,15'
- ALL: Milestones-Plans-Risks for modeling & use cases(3rd-4TH iteration), 5'
- ALL-Kosta-Cindy S&I LRI communication and subgroups, 5'
- ALL-HL7 ballots May-cycle (EHR, clinical, blood, gen testing etc) 5'
- ALL-Galen: Information Modeling (classes, patterns, granularity),30'
- ALL-Kosta-Neelima-Cindy-Ira : Discuss cases and subgroups, Terminology 5'
- ALL: Lab-OO interfaces, FHIMS domains, NHIN Direct, HIMSS, HL7 Lab-OO,2'

Action Items

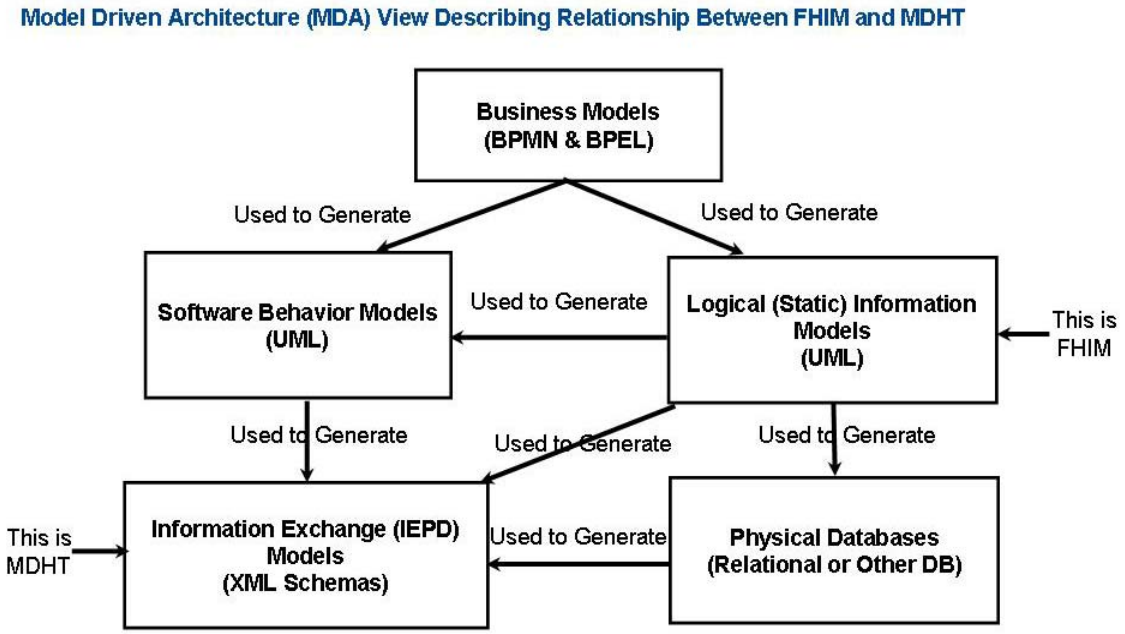
Start Date	Priority	Action Item	Status
11/22/10	Low	7) Wendy-Kosta-Galen-Cindy: Clarify Specimen-Sample filler and placer order nr, test identifier, placer group number and universalServiceIdentifier. The Pathology Lab uses specs from DICOM (Supplement 122, specimen, accession number, etc) in workflow.	In process
11/22/10	Low	8) Kosta-Steve Hufnagel: Services Aware Interoperability Framework and Lab-OO FHIMS relevance (Lab-OO 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

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 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

Appendix

by Steve Wagner (AAAS11 Lab-poster)



By Kosta Makrodimitris (conceptual maps for FHIM, General FHIMS meeting 2011-03-25)