FHIMS Lab Domain:
Order, Perform, Observe, Interpret, Store, Report, Receive
Meeting Minutes (July 25th)
Agenda for the next meeting (August 1st)

Date/time of call:
Monday, July 25th 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

Mike Fitch, DoD
Kosta Makrodimitris, FDA
Anand Shukla, VA
David Bass, VA
Steve Wagner, ONC
Anne Pollock, CDC
Ira Lubin, CDC
Glenn (Randy) Hatfield, VA

Agenda

- ALL- Milestones-Plans-Risks for modeling & cases (4th iteration), 5'
- ALL- Ira: genetics use case, breast cancer 30'
- ALL- Kosta-Cindy S&I LRI , 25'
- ALL- PHI-CDC presentation in August 5'
- ALL- Kosta Public Health reporting and Lab (new domain FHIMS-S&I) 5'

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

Clinical Modeling Meeting (addition from the July 18th call)

- Galen was invited to and attended a Clinical Modeling Meeting called by Stan Huff, Medical Director of Intermountain Healthcare in Utah. This meeting started from the HL7 Fresh-look effort which spun off a clinical information model (CIM) and repository effort. They want to define a single notation for these CIMS that will work for clinicians as well as information technology professionals.
    - Clinicians prefer the OpenEHR notation. This notation shows clinical information as a mind map and is, therefore, not easily implemented in IT systems.
    - HL7 has the specialized, proprietary notation and modeling style of the RIM and its children models including detailed clinical models (DCMs).
    - Some IT professionals would like to use UML which has many different possible models and can be used to generate and implement system code including databases.
    - Each approach has their own, nearly competing viewpoints and perspectives. OpenEHR uses as "bottom-up" approach starting with the Clinician's viewpoint, while HL7 starts with the RIM and constrains it down to get the exchangeable data.
    - In short, the CIM/DCM modeling "language" is still being selected.
- Can these CIMs and DCMs be associated with the FHIM? Are there use cases available? How do these CIMs/DCMs lead to functions and data fields that are assumed to be in the IT system such as an EHR and/or LIS? Basically, use cases seem to be the pinnacle and, therefore, starting point, but this group doesn't seem to have a repository of use cases and/or scenarios.

Information Modeling

- Galen - The Microbiology Result class may need to be updated to contain more information.
    - Anne - Why do we even have "microbiology" identified as a class? A lot of non-microbiology results have the same result structure.

- Mike, all - How to model any relationships that may exist between various orders, promises, specimens (e.g., urine and serum for creatinine clearance), results (e.g. elements of a panel), interpretations (e.g., Resistant, Susceptible, Intermediate, Moderately Susceptible), reports (e.g., 0 to many preliminary report(s), a final, and 0 to many amendment(s)), etc. Most of the examples used were in microbiology, with explanations of the meanings of MIC (minimum inhibitory concentration) along with its susceptibility interpretation and potential use in therapeutic blood concentration monitoring. Mike suggested caution that we or the model don't artificially introduce the perception of an association that really doesn't exist. Anne reemphasized the inherent variability in how different labs and persons arrive at their conclusions and that we must guard against attempting to model the "how."

Planning

- Kosta will be finalizing the 3rd iteration report that is posted on OHT Tools which includes plans for this 4th iteration and timeline

CDC-PHIN conference in August

- Kosta - FHIMS Lab will be presenting at the PHI Conference August 22 - 24. Cindy, Nikolay, Kosta me to prepare some slides for the presentation
  http://cdc.confex.com/cdc/phi2011/webprogram/Session12682.html
  Preliminary outline (Kosta-Cindy-Nikolay)
    - Acknowledgement CDC, ONC, FDA
    - Background (HITSP, HL7, CLIA, CAP, LOINC)
    - Purpose – open dialogue, ONC, cases
    - ONC/FHA/FHIMS
    - FHIMS/Lab domain Process, Methodology, Progress, Focus models
    - S&I LRI PH collaboration – S&I (learning objectives models and cases)
    - Goals-Objective PH focus

- Public health initiative-domain FHIMS
- Business proposition, purpose
- Use cases (test-reports-results) lab component, Furure efforts– C

Information Mapping

- Galen - Mike, Anne, Cindy continue exploring and studying classes/definitions within the model that have not been completed reviewed or understood. Some classes are removed. Full report pending in August.

Blood Banking

- Mike/Anne

Blood bank isn't dramatically different from other modeling efforts we've already discussed except that it involves the dispensing of an actual product which we must manage and track. We also discussed why we generally differentiate the blood bank practice into at least 2 subsections which we refer to as Donor Services and Transfusion Services.

Donor Services incorporates all the donor management, product collection, blood unit testing, component preparation, labeling, etc. It's here that FDA considerations are significant because (1) it involves maintaining personal medical and history information on non-patients (the donors), and (2) the collection and preparation of the blood products themselves fall under the Good Manufacturing Practices overseen by the FDA and others.

Transfusion Services generally starts with the blood products already having completed the manufacturing" processes, are cleared, and are already in the inventory available for patient use (in many ways, this is similar to managing FDA-cleared drugs in a pharmacy). Transfusion Services includes inventory management (including requesting and shipping cleared products among blood banks), compatibility testing, immunohematologic patient testing, blood product dispensing, infusion, and post-transfusion patient and unit management (which includes transfusion reaction workups as necessary).

It's my recommendation that we focus our initial modeling efforts on Transfusion Services. Not only does this eliminate the FDA concerns, it represents the therapeutic activities associated with clinical treatment practices and therefore also the data that flows between physician, bloodbank, and between EHRs.

Related to FDA Medical products----blood, device, drug, proteins

Genetics Use Case

- Ira presented the business case and flowchart model. He made recommendations on how to simplify this for the potential PHI presentation of the case(1 slide) to capture a couple essential elements
- What is the value and roadmap for lab/FHIMS cases
  a) Map and validate the model
  b) Create additional artifacts for agency business cases, EHRS functions
  c) Implement realistic scenario for FHIM/lab that cross different results/categories
  d) Clarify actors in the lab/FHIM to model behavior
  e) Follow and link with S&I framework (from cases inception to standards)
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- HL7 ballot for Sep 2011 on genetic testing reports http://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm?action=edit&ProjectNumber=460
- HL7 ballot for Sep 2011 on LOINC-Qualified Cytogenetic Model http://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm?action=edit&ProjectNumber=663

S&I LRI Communication

- Kosta - S&I LRI is in the final stages of developing the implementation guide.
- Kosta – S&I F public health reporting initiative had first meeting and charter presentation

The S&I Public Health Reporting Initiative was held on Wednesday 07/27 4:00pm-5:00pm ET. More than 70 Public Health participants attended,

Where 1-408-600-3600 Access code: 661 274 472
Description: https://siframework2.webex.com/siframework2/onstage/g.php?t=a&d=661274472
Agenda:
4:00-4:05 Welcome and Introductions, Wendy Scharber
4.05-4.20 Public Health Reporting Initiative Logistics and Next Steps, Merideth Vida
4:20-4:40 Review of the PH Reporting Initiative Charter, Anna Orlova, Co-lead
4:40-4:55 Review of the PH Reporting Initiative Summary, Kosta Markodimitris, Co-lead
4:55-5:00 Other
Call Materials (attached):
· Public Health Reporting Initiative Draft Charter
Wiki URL: http://wiki.siframework.org/Public+Health+Reporting+Initiative

Terminology

- No terminology for lab domain this week. Meeting was focused on Person.

S&I LRI Communication

- Kosta – The S&I LRI focus on Implementation Guide(draft informative HL7 ballot) and vocabulary issues to meet the deadlines(leadership minutes) http://wiki.siframework.org/LRI+Implementation+Guides+Analysis+WG
- Kosta – Participated in consensus meeting for use case simplification WG(Gary Dickinson,EHR mapping, drill down cases etc). New artifact on actors

FHIMS & S&I (LRI) Mapping

- Approximately 80 - 90% of the elements requested by S&I LRI are in the FHIMS Lab model. Neelima will get with Galen to review the mapping and update the FHIMS elements to reflect the latest model.
- S&I LRI work for an HL7(informative) draft IG http://wiki.siframework.org/LRI+Implementation+Guides+Analysis+WG
- S&I PH will be it's own initiative next week driven by community-stakeholders and pending approval for funding by ONC. PHDSC will support the initiative(technical) http://wiki.siframework.org/

HITSP C32/C36 and C80/C83, CDA & EHR-FM XML

- Steve Hufnagel recommends that FHIPS lab review the HITSP documents CAP99, CAP126, CAP127, C36, C37, C80, & C83 (for the specimen and lab components) for information that may need to be included in the FHIM lab model or for references to other documents that will need to be reviewed to locate information that may need to be included in the FHIM lab model. www.hitsp.org

ANNOUNCEMENTS

- Pathology Informatics 2011 October www.pathinformatics.pitt.edu
- Public Health Informatics conference this summer in Atlanta: Engaging, Empowering, Evolving…Together Aug 2011 http://www.cdc.gov/phiconference/index.html
- CLIA conference in aug-sep 2011 http://wwwn.cdc.gov/cliac/

Agenda Next Call: August 1st 2011

- ALL- Milestones-Plans-Risks for modeling & cases (4th iteration), 5'
- All Information modeling and classes 30'
- ALL- PHI-CDC presentation in August 5'
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Action Items-(NEED UPDATE after planning 4th iteration)

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
04-14-2011	**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
04/04/2011	**High**	35) Cindy-Anne prepares definitions and document on ambiguous terms (ELR, EHR)	Completed