FHIMS Lab Domain:
Order, Perform, Observe, Interpret, Store, Report, Receive
Meeting Minutes (June 27th)
Agenda for the next meeting (July 11th)

Date/time of call:
Monday, June 27th 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

David Bass, VA
Mike Fitch, DoD
Kosta Makrodimitris, FDA
Galen Mulroony, VA
Anand Shukla, VA
Steve Wagner, ONC

Agenda

- ALL: Milestones-Plans-Risks for modeling & cases (4th iteration), 15'
- ALL-Galen: Information Modeling and mapping report update(C36 etc)15'
- ALL-Ira: genetics use case, breast cancer 15'
- ALL-Kosta-Steve Terminology Lab 5'
- ALL-Steve-Galen FHA report 5'
- ALL-Kosta-Cindy-Neelima-Galen S&I LRI , 5'
- All – Kosta Public Health reporting and Lab (new domain FHIMS-S&I)

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

Genetics use case

Ira Lubin(CDC)

1) We need to focus on the elements of modeling and EHR transmissions, not necessarily the "laboratory diagnostic arts" used in analysis/interpretation or the diagnostic/interpretative/predictive/therapeutic/etc. effects managed by the laboratory.

comment: It is not clear how genomic data will be managed. It is conceivable that such data will be "deposited" in a database outside the laboratory's purview for future reinterpretaton. At this point in time (and the near future) it is unlikely that raw data will leave the laboratory. More likely, one of two levels of data will are needed - 1) sequence variations identified determined to be clinically significant and/or 2) all sequence variations determined with those determined to be clinically significant noted. In both cases, current good laboratory practices suggest the reference sequence used in making these conclusions be cited (by name for lookup). The advantage of #2 is that it permits future reanalysis of all sequence variants.

2) What is different about genetics orders and results from a systems/modeling perspective? comment: I would not say unique but rather some attributes of genetic testing are emphasized in importance
   a) Test results often have both diagnostic and predictive implications. Many tests are ordered as predictive tests for asymptomatic individuals to assess carrier status or disease risk based upon family history or other indications.
   b) Test may be ordered on and/or performed on and/or resulted on someone (or even something) other than the patient. comment: there are informed consent issues
   c) Result often have an implication(s) for someone other than the patient (issues are somewhat similar to HIV testing and follow up with partners)
   d) Proper analysis often requires
      i) knowledge of patient's race/ethnicity and/or family history
      ii) knowledge of genotype/phenotype correlation/ disease natural history, etc. available through external databases. There is a corollary in the the infectious disease world with respect to ribosomal RNA sequencing to type bacterial strains.
   e) Potential to identify non-paternity (this is also an issue for HLA testing but in many systems this information is available but not assessed or reported with cross-matching is performed)
   f) Report structure may be inadequate due to the volume of information. There are two aspects to this - the data used to generate the report through transmission to the EHR and the report generated that is provided to the physician. The latter should not be a problem. The former challenge at present is not considered to be the volume of information but rather adequate machine coding of some key information, such as family history/race ethnicity. At present, raw and partially processed data will remain within the laboratory environment and this is a challenge for the laboratory but probably less so for our purpose (for human genome this can involve several terabytes of data that the laboratory will collect and process. Following laboratory processing, we are down to the megabyte level of data).
3) Are there other non-genetic laboratory analogues to these unique items? Yes - HIV and HLA testing.
   a) Testing on someone other than the patient for the patient’s benefit
      i) Crossmatching Mom to transfuse newborn (per above - paternity can be assessed but often is not even when data is available)
      ii) Public health contact testing (not currently implemented for genetic conditions. We have had a number of focus groups and physicians have voiced strong opinions that their responsibility stops in informing the patient about familiare implications. However, public health databases were seen as a potential resource for identifyng at-risk familymembers.)
      iii) Blood bank lookback processes
      iv) “Needlestick” source and victim procedures
   b) Results with implications for others
      i) Communicable organism identification
      ii) Failed sterility checking
      iii) Blood group, type, and antibody identification (also has a genetic component)
   c) Need for external databases or other information resources
      i) Organism identification/characterization based on reactions, sensitivities, etc.
      ii) Serotyping (genetic or other methods)
      iii) Tumor registries

iv) Result confirmation and/or validation
v) Quality control records (these are anonymized)
vi) Information required to be submitted with the order (e.g., dose time for peak and trough, lots of gestational data for AFP, % supplementary oxygen, etc.)

d) Report structure inadequacies

4) Can current models already support these genetics-unique items?
   a) (Testing for someone else) No, but this also has non-genetic ramifications.(I would argue that partner testing for HIV infected individuals might be a model)
   b) (Implications for someone else) Yes, assuming the other persons are known, legalities are addressed, and appropriate results are added to their records as well.
   c) (Need for external data sources) Yes, though not necessarily in an automated fashion.
   d) (Report differences) Maybe, given the models provide for unlimited size.
   e) Informed consent / HIPAA issues - need to be investigated. We may need to consider, in some instances, building in a switch to either make data available or blocked based upon the presence or absence of informed consent.

Kosta-Ira Discuss the CDA Implementation Guide for Genetic Testing Report (GTR): Towards a Clinical Genomic Statement (IHIC 2011, Dr Shabo)
http://www.hl7.org/events/ihic2011/papers/friday/F_Q2_4_CDA%20IG%20for%20Genetic%20Testing%20Report%20-%20IHIC%202011%20-%20Shabo%20%5BCompatibility%20Mode%5D.pdf

Mike Fitch- *I agree with all your comments and expansions (e.g., the HIV partner testing, along with STDs and other contact/communicable/reportable disease testing, is all part of the Public Health testing referenced earlier in the outline but certainly merits the elaboration you provided). Based on our assessments, it appears that genomics should become part of our ongoing discussion on what "divisions" of business/process/reporting our model merits--if any--based on their relatively few significant data differences: chemistry, hematology, coagulation, serology, urinalysis, TDM, etc. (a.k.a., results with possible reference ranges); microbiology, perhaps further subdivided (e.g., bacteriology, virology, parasitology, TB, mycology, etc.); anatomic path, again perhaps further subdivided (e.g., surgical, bone marrow, cytology [gyn and non-gyn?], autopsy, etc.); blood bank/transfusion service; genetics/genomics; perhaps others.*
Ira- *I added some comments. In my view, HIV and HLA (serologic - certainly a form of genetic testing) testing share many of the attributes of genetic tests. Genetic testing in a sense is not unique but places emphasis on certain testing components somewhat different from other tests, such as the importance of family history and implications for other family members. Also, at the present time, there seems to be a perceived "genetic exceptionalism" within our society placing genetics into its own category when in fact it is probably more cross-cutting. Perhaps one important nuance is an emphasis on predictive tests used to assess carrier status or risk for disease. There is a correlate to cholesterol testing in this regard although test ordering and reporting processes differ in several but not all aspects.*
Kosta –Pharmacogenetics is a very important case for USFDA now and Abacavir might be a good one to model. http://www.fda.gov/Drugs/ScienceResearch/ResearchAreas/Pharmacogenetics/ucm083378.htm
Galen-Ira - One aspect of genomics and some other labs is that there isn't necessarily a diagnosis. Sometimes you're looking to see if someone is a carrier for a condition, but might not (e.g., cystic fibrosis) Sometimes you might have a partial diagnosis and the genomic data will refine the diagnosis
Often, you're looking at a sequence of bases that have no meaning without context - especially the disease or condition that is involved or suspected to be involved.
How to we take complex genomic data (which may be correlated with additional data) and present it in a digestible format for the clinician?
ALL-Ira-Mike In any sequencing study, you will find variations - some will be normal variations, while others might be associated with a disease state or condition. You therefore need to query a database of sequences to determine whether the sequence variations are normal or not. Sometimes these databases are internal, part of the software package; often they are external, which may include results of various studies. Frankly, this isn't all that different from other lab tests - to determine whether a result is "normal", reference must be made to a body of knowledge. Again this body of knowledge may be built into the software (especially in typical lab tests), but may be queried of an external database (especially for atypical tests). Need to model family medical history. It's important to distinguish between predictive tests versus diagnostic tests. The data might be very similar, but the emphasis is different.

Information Mapping

- Galen - Neelima and Galen have not been able to get together. They are working on mapping HITSP C36 to FHIMS Lab. Steve Wagner would like to take that mapping to the S&I LRI group so they can use it for their purposes. Galen said that 80-90% of mapping to S&I LRI and has been done
    - Kosta – there are 3 guides that LRI IG teams are trying to harmonize HITSP-C36, ELINCS, ELR2PH http://wiki.siframework.org/file/view/A%20high-level%20comparison%20of%20the%20three%20guides%2C%20summarizing%20notable%20differences%20and%20similarities.pdf

S&I LRI Communication

- Kosta – The S&I LRI focus on implementation guides and vocabulary issues to meet the deadlines(leadership minutes)
- Kosta – Participated in consensus meeting for use case simplification WG(Gary Dickinson,EHR mapping, drill down cases etc)

Terminology

- Kosta - The Terminology group met this Wednesday. There are problems with class/attributes definitions that a focused team will try to finalize before start working with terminologists possibly next couple weeks

Planning

- Kosta - We have 7 meetings remaining for the rest of the summer (next 2 months). We need to plan accordingly since we have limited resources this summer.
- Kosta - The FHIMS Lab Domain abstract has been accepted at PHIN-CDC http://cdc.confex.com/cdc/phi2011/webprogram/Session12682.html . Kosta will present in August in ATLANTA.
- After mapping to C36, we may want to validate the model (Cindy, Neelima, & Mike agree). We have spent a lot of time talking about specimen, anatomic pathology, and various results (titers, microbiology, etc); we need to ensure the model is complete and accurate.
- Kosta- We should complete this report this iteration. I uploaded the report with high-med-low (for this iteration items) in OHT wiki space. Please edit and share. https://www.projects.openhealthtools.org/sf/docman/do/downloadDocument/projects.fhims/docman.root.information_domain_documentation.docf1105/doc1745

FHIMS & S&I (LRI) Mapping

- Approximately 80 - 90% of the elements requested by S&I LRI are in the FHIMS Lab model.
- Next steps: Neelima will get with Galen to review the mapping and update the FHIMS elements to reflect the latest model.

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
- Visualizing the 21st Century of Healthcare Today http://www.govhealthitconference.com/
- Public Health Informatics conference this summer in Atlanta: Engaging, Empowering, Evolving…Together Aug 2011 http://www.cdc.gov/phiconference/index.html
- SOA in Healthcare conference http://www.omg.org/news/meetings/HC-WS/index.htm July 2011
- CLIA conference in aug-sep 2011

Agenda Next Call: July 11th 2011

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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