FHIMS Lab-Orders and Observation Domain
Meeting Minutes (March 7th)
Agenda for the next meeting (March 7th)

Date/time of call:
Monday, March 7th, 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
Mike Fitch, DoD
Nikolay Lipskiy, CDC
Kosta Makrodimitris, FDA
Galen Mulrooney, VA
Anne Pollock, CDC
Anand Shukla, VA
Cindy Vinion, NG/CDC
Steve Wagner, ONC

Agenda

- ALL-Kosta-Anne-Nikolay: International Society for Disease Syndromic Surveillance business processes and requirements (15')
- 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

ISDS

Resource used: *Core Business Processes and EHR Requirements for Syndromic Surveillance*

- Kosta - This document seems to be related to meaningful use per the HITSP Biosurveillance Interoperability Specification (IS02). The ISDS document is directed to emergency departments (EDs) and urgent care (UC) providers. The process is for ED and UC to report information to public health for syndromic surveillance purposes.
    - Nikolay - The ISDS document is about reporting for syndromic surveillance & not limited to biosurveillance. ISDS is still struggling with scope and definition. For example, the difference between case reporting and reporting for syndromic surveillance has not been fully explored and defined. Syndromic surveillance, biosurveillance, and public health reporting are terms that need more work to define and scope.
    - Kosta pointed out the figure on the report about Development Process for the Draft Minimum Data Set which shows the relevance to HITSP and AHIC cases.
    - Nikolay put more emphasis on the Minimum Data Set outcomes presented at the end of the report.
- Kosta gave an overview of the report regarding the PHSS context (where lab fits), key assumptions and business process model principles.
- Nikolay - Current biosurveillance at the CDC, such as the BioSense system, uses HL7 ADT (Admission, Discharge, and Transfer) messages for syndromic surveillance. Currently, the data is very limited and primarily contains chief compliant, an initial diagnosis, and some information collected during the initial examination.
    - Anne - The initial exam may include results from waived testing. Testing using devices reviewed and evaluated by the FDA as "waived". In short, anyone can use these devices to perform a test following the instructions.
    - From Federal Register, September 13, 1995 (Volume 60, Number 177), Public Health Service; CLIA Program; Categorization of Waived Tests (http://wwwn.cdc.gov/clia/docs/hsq225p.htm):
      "As currently defined in the regulation, waived tests are simple laboratory examinations and procedures that--
      (1) Are cleared by the Food and Drug Administration (FDA) for home use;
      (2) Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or
      (3) Pose no reasonable risk of harm to the patient if the test is performed incorrectly."
    - Cindy - The FHIMS Lab model will need to include waived testing data even if the data is not currently part of any surveillance implementation guide or interoperability specification.
    - Nikolay - Nikolay can share the new CDC syndromic surveillance guide. It hasn't been released yet, but will be in the next couple of days.
- Cindy - It would be nice to get some written use cases or scenarios written to explain the public health analysis functions called for in the ISDS document.
    - Anne - We need to know why agencies are or want to receive the data.
- Galen - We might want to map these new syndromic surveillance requirements and guides to the full FHIM model. It might be helpful to have a Surveillance sub-group to work on this mapping.
- Mike - We need to be sure that "lab data" is defined for the purposes of the FHIMS-Lab. It can be 'data created and sent by a lab' or 'information created and/or captured during testing'. The second one could include the waived testing performed at a provider's location while the first one would not. It may be that the information is narrative rather than structured when it is captured by a provider.
    - Anne - Public Health would like to look at all "laboratory data" regardless of where it came from - lab or provider.
    - Galen - The modeling of lab data is not limited to the information generated by a lab during the testing process.

- Cindy & Mike - FHIMS Lab needs to ensure that both lab and provider use cases are accounted for in the model. Results will also need to be stored as narrative and more structured constructs.

Modeling

- Galen - From the VA starting model, chemistry tests have reference ranges and abnormal flags but biological testing does not. This may not be true for the FHIMS Lab model.
    - Cindy & Anne - The statement is not true. Some biological tests, such as serology tests with titers and tests that measure virus or agent concentrations may have either or both reference range and abnormal flag.
- Anne - Why not look at lab data in general rather than break it out by chemistry tests and biological tests?
    - Mike - VA and DoD grouped a lot of tests together by structural commonality and called them all "chemistry tests"; however, that does not mean that the tests only measure chemicals.
    - Cindy - If that is true, then the classes that are currently classified as "chemistry" are not just chemistry; therefore, the classification should be removed from the name of the classes. Doing this would remove the chemistry/biological breakouts and create general laboratory classes per Anne's suggestion. By doing this, we'd have a test class that would contain the information about what was ordered and/or looked for with result class(es) that would contain the appropriate result structures.
- Cindy - Cindy suggests using CLIA to begin adding the attributes to the classes that were created to reflect the CLIA categories. Doing this would begin the process of detailing the classes from a CLIA perspective which we could, then, add to the FHIMS Lab model.
    - Kosta - We all need to look at the meaningful use requirements (final rule) and how they define the structured data to link with the metrics for EHR certification.
    - Anne - Meaningful Use points to CLIA, so starting with CLIA is appropriate.
    - Kosta - There are other requirements and regulations that need to be considered and added to FHIMS Lab. For example, CLIA does not necessarily apply to food testing; the FDA has other regulations. EPA the same. It's not just health exchanges but research, regulation etc.
    - Cindy - There are many requirements and regulations we will need to add. But, by starting with CLIA, we will get a great start and can add other regulations in the future. Please collect the needed requirements for consideration later.
- Kosta suggested that the lab categorization that the group implemented according to CLIA na othe experts opinion to keep it as a permanent structure of the information model for several reasons:
    - Lab reports/orders can include combination of different lab categories(genetic, chem., tox etc)
    - Use cases can link to different lab categories and sub-domains can work on mapping
    - In the future relevant lab experts can give more input about the data to add more level of details
    - Since we represent the Lab domain it's important to define lab types of data and to work always on their commonalities, differences and combinations for different agencies and exchange scenarios

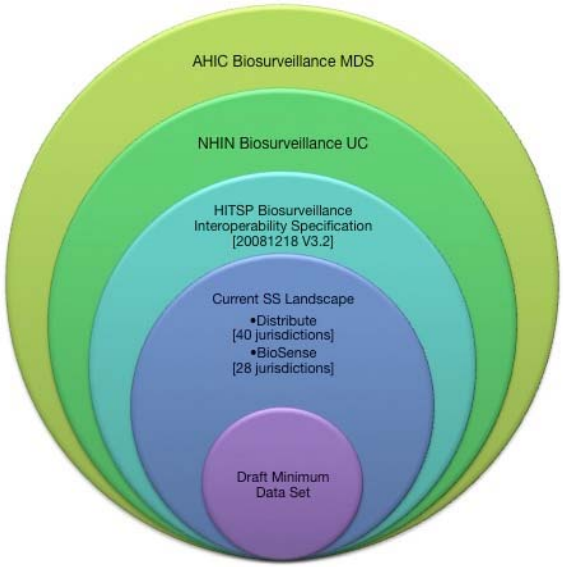
General Discussion

- Kosta - Some discussions, particularly with the Cancer Registry people, are highlighting the importance of reporting and lab reports when exchanging lab data. He mentioned the importance of having subdomains and sub-WG in each of them. There are going to be different subgroups folders in OHT . An initial list of subWGs:
    - EHR-Lab (in, out-patient) HITSP standard case-Cindy-Anne all
    - Genetics/Molecular combination-Ira
    - Cancer registry-Sandy
    - Food safety(FERN, eLEXNET)-Kosta
    - Sentinel(drug-device) lab types/EHR year2-Mitra
- Kosta would like to change the name of the Lab domain from Lab - Orders and Observations to Lab - Orders, Observations, and Reports (Results) or something that describes the whole scope and process of the domain. The HL7 Orders and Observation name is not descriptive enough.
    - Cindy - Cindy thinks that adding "Orders and Observations" causes unnecessary confusion and the name of the group should simply be "Lab Domain". That name is sufficient to indicate to everyone reading the title that this domain is dealing with lab data and only lab data. The HL7 Orders and Observations group is not limited to lab, it covers any/all order and any/all observations. FHIMS Lab is limited to lab information only; adopting the HL7 working group's name is not helpful.

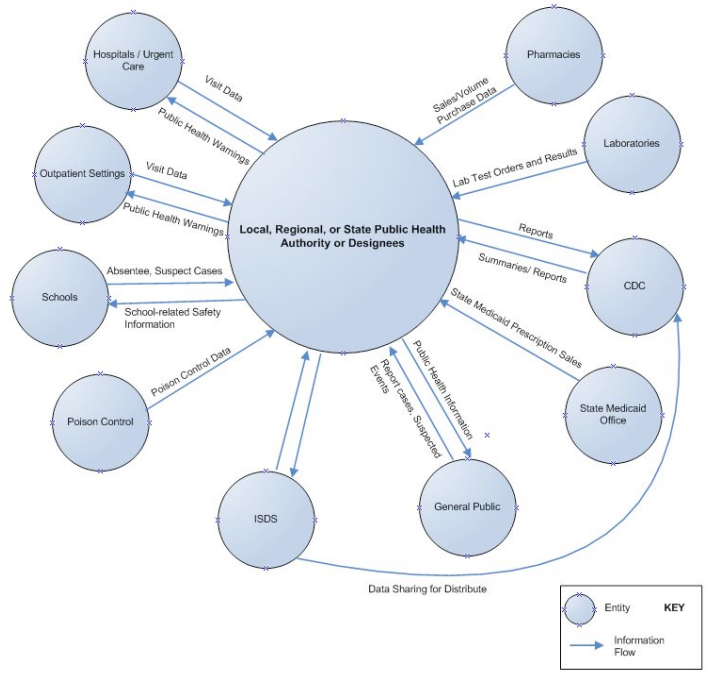
Anne & Galen - Agreed with Cindy. The scope of the lab domain can be explained as part of the domain's information. Kosta agreed that this is a good option but to make always explicit the scope of the domain avoiding ambiguity with the scope of the other FHIMS domains, S&I, experts. Perhaps we need a full dictionary of all FHIMS domains.

RESOURCES

- *Provisional RecommendationCore Business Processes and EHR Requirements for Syndromic Surveillance http://www.syndromic.org/uploads/files/ISDSRecommendation-PROVISIONAL_vFINAL.pdf*



Syndromic Surveillance Context Diagram



Business process models describe the means by which organizations accomplish a goal to produce something of value. These models detail the consecutive tasks or task sets through which value is added. In contrast to use-cases, business process models provide a holistic picture for understanding how an information system can add value for its users and interface with other organizational activities to build efficiencies.

- S&I LRI UCR Structured Data Sub-Workgroup page and read the comments 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 14th 2011

- 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')
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Action Items

Start Date	Priority	Action Item	Status
11/22/10	Low	7) Wendy-Kosta-Galen-Cindy: Clarify Specimen-Sample filler and placer order number, test identifier, placer group number and universalServiceIdentifier. The Pathology Laboratory uses specs from DICOM (Supplement 122) to describe the various units (specimen, accession number, etc) in workflow.	In process
11/22/10	Low	8) Kosta-Steve: 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 domain - filler order number, placer order number, group number, test identifier, etc.	In process
11/8/10		10) Need to discuss different scenarios involving different people (ward clerk, nurses, physicians, physician's assistants, interns, etc) and who those people would be 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		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, slated for 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)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 . Kosta may invite some experts for Medical Countermeasures from the FDA agency and collaborating contractors.	In process
11/08/10	Low	19)Galen to update weekly the FHIMS Lab-OO 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 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). Present and organize library of BPMN cases.	In process
11/17/10	**High**	**23) Kosta-Cindy-Galen-Steve: Plans and documentation of modeling efforts and cases during the next 3 meetings as the end of the 2nd iteration of the Lab-OO. Schedule and plan the 3rd iteration Jan-April 2011**	**In process**
03/4/11	**High**	**24) Kosta-Galen Create space for 4 sub-WG under Lab-OO**	**In process**
03/4/11	**High**	**25) ALL Business cases diagrams and data exchange elements to standarize**	**In process**
2/28/11	**Med**	**Kosta – llead S&I subWG to Develop definitions for structured and unstructured data**	**In process**

Completed/Not Tracked Action Items

Start Date	Priority	Action Item	Status
11/8/10		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
11/1/10	Low	4) Cindy to send flow chart PDF to Anne Pollock	Completed
10/25/10	Low	3) Kosta-Galen will organize the OpenHealthTools shared project space for Lab-OO, Update 11/1: Steve working on organizing the OpenHealth tools project space	Completed
10/25/10	High	2) Prepare for FHA leadership meeting to present FHIMS domains process (Steve-Sean presented,Nov-2010)	Completed
10/25/10	Low	1) Initiate a dictionary of terms and definitions for Lab (Cindy, draft)	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