FHIMS Lab-Orders and Observation Domain
Meeting Minutes (January 10th)
Agenda for the next meeting (January 17th)

Date/time of call:
Monday, January 10th , 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
Kosta Makrodimitris, FDA
Danny Martin, TSJG/ICLN
Cindy Vinion, NG/CDC

Agenda

- ALL-Kosta-Anne: International Society for Disease Surveillance documentation
- ALL: Lab class definitions for the models
- ALL: Milestones-Plans-Risks for modeling & use cases(3rd iteration)
- ALL-Kosta-Cindy: Discuss use case and scenarios

Summary of Discussion

PCAST Comments

- Kosta: Steve Wagner would like us to submit comments, both good and bad, for the PCAST Health Information Technology Report (see http://www.whitehouse.gov/administration/eop/ostp/pcast/docsreports). Should the comments from the Lab-OO group be more lab-centered and/or discuss our process.
    1. Cindy feels that this report is very high-level and strategic and that the more tactical or operational process that Lab-OO is following should not be part of the submitted comments. FHIMS and the Lab-OO are already doing actions that can satisfy the PCAST recommendations; and, that should be communicated.
    2. Kosta supported that the document is for a broad audience and in certain cases make technical recommendations without taking into account current available solutions and background. Perhaps we can give them some FHIMS(DOMAIN) oriented feedback and cases and provide technical perspective. ONC requested in FR some specific comments.

Lab-OO Model Class and Attribute Definitions

See FHIMS Lab Definitions
https://www.projects.openhealthtools.org/sf/go/doc1581?nav=1

- Many of the classes in the report from the model have not been modeled by the Lab-OO group and cannot be reviewed; these rows have been identified with colored text.
- Mike mentioned that he did not understand BiologicalEntitySpecimenCollection, which has no definition, or its attribute, bodySite. We will need to wait for Galen to complete this review.
- Cindy mentioned that some of the definitions we have decided upon for FHIMS Lab-OO are in the lab term document on OHT (https://www.projects.openhealthtools.org/sf/go/doc1562?nav=1)

Other Discussion

- Kosta: When Tim Morris presented the ICLN model, he mentioned some definitions or a data dictionary; can Danny check on that document to see if FHIMS Lab-OO can have a copy. Tim shared finally the data dictionary and it's uploaded in OHT.
- Kosta shared the following announcement for applicability to FHIMS Lab-OO: HL7 Version2 Transmits Genomic Data to EHR http://www.medicexchange.com/EMR/hl7-version2-transmits-genomic-data-to-ehr.html#
- Kosta informed about the new food law, the Food Safety Modernization Act (FSMA), which appears to be relevant to labs reports and accreditation and certainly will impact those labs participating in the Food Emergency Response Network (FERN). Information about this act from the Institute of Food Technologist (IFT) may be found at http://www.ift.org/food-technology/newsletters/ift-weekly-newsletter/2011/january/011011.aspx#headlines1. Please review this review for applicability to FHIMS Lab-OO.
- When a document (*.docx) or spreadsheet (*.xlsx) is uploaded to OHT, OHT is changing the file into a zip file containing many XML files. This does not happen to

files saved as either .doc or .xls files, and did not happen in the past (1st file where this happened is Dec 27). Cindy will contact Sean Muir about this issue to see if we can get it corrected. When you upload in Office2003 format there is no problem(K)

- Since next Monday, January 17, 2011, is a Federal Holiday; we will cancel the Lab-OO meeting.

Provided Resources

- From ISDS: Core Business Processes and EHR Requirements for Syndromic Surveillance. Available on OHT at https://www.projects.openhealthtools.org/sf/go/doc1582?nav=1 and at http://syndromic.org/uploads/files/ISDSRecommendation-PROVISIONAL_vFINAL.pdf
- FHIMS Lab Definitions. Available on OHT at https://www.projects.openhealthtools.org/sf/go/doc1581?nav=1

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 . 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	20)Kosta-Galen-Cindy-Steve-Neelima to prepare and design a FHIMS-Lab-OO poster accepted for AAAS meeting in DC(Feb-20th 2011)	In process
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

Start Date	Priority	Action Item	Status
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

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
12/3/10	Low	24) Kosta updated minutes, material, HL7 2.5.1 resources, HITSP cases in OHT shared space	Completed

Agenda Next Call: January 17th 2011

- ALL-Galen: Modeling Information and decide on classes, patterns and granularity
- ALL-Kosta-Anne: International Society for Disease Surveillance cases-report(10')
- ALL-Kosta-Neelima-Cindy: Discuss use case and scenarios (10')
- ALL: Lab class definitions for the models(5')
- ALL: Milestones-Plans-Risks for modeling & use cases(3rd iteration) (5')
- ALL: S&I Lab, NHIN DIRECT lab, HL7 Lab-OO,(5')

Appendix

http://www.medicexchange.com/EMR/hl7-version2-transmits-genomic-data-to-ehr.html#

HL7 Version2 Transmits Genomic Data to EHR

Thursday, 21 January 2010 05:27 |

View Comments

HL7, announced its Version 2 messaging standard has successfully gathered structured and coded genetic tests results from a lab and transmitted them to an individual patient's EHR for the first time.

The current standard for genetic test results is either paper or electronic narrative reports. The guide, titled HL7 Version 2 Implementation Guide: Clinical Genomics; Fully LOINC-Qualified Genetic Variation Model, Release 1, details structuring a genetic test result into the EHR utilizing HL7 Version 2.5.1. It is based on both the HL7 Version 2 Implementation Guide Laboratory Result Reporting to the **EHR**, and the HL7 Version 3 Genetic Variation data model.

The guide covers the reporting of genetic test results for sequencing and genotyping based tests where identified DNA sequence variants (i.e. mutations) are located within a gene. This includes testing for DNA variants associated with disease and pharmacogenomic applications, such as predicting a patient's responsiveness to drug therapy and drug metabolism rate. It is fully-LOINC qualified, meaning that new LOINC codes have been created to represent the test components and results. LOINC codes offer the consistency of representation across different message types and for clinical decision support.

The implementation guide was used by The Partners HealthCare Center for Personalized Genetic Medicine (PCPGM) and the Intermountain Healthcare Clinical Genetics Institute to gather genetic test results and transmit them to an individual patient's electronic health record for the first time. The results were sent by a direct computer interface from PCPGM to Intermountain Healthcare.

"This work aligns with national efforts to re-examine and improve healthcare delivery," says Mollie Ullman-Cullere, PCPGM senior information architect and co-chair of HL7 Clinical Genomics Work Group. The work group is comprised of volunteers who come from prominent healthcare systems, major laboratories, and leading healthcare IT software vendors.

"The project is among the first in the country that will create a standardized advanced electronic patient record system containing genetic data," says Stan Huff, chief medical informatics officer for Intermountain Healthcare and HL7 International board member. "This may lead to the electronic health record of the future, which would support treatment plans that are tailor made for each individual — right down to their DNA."

Huff's team at Intermountain Healthcare worked with Partners HealthCare for 14 months to build the framework for receiving test results and integrating them into a patient's electronic health record. During this time the Partners team developed a lab reporting system that would create and send out the test result message through a centralized interface hub. Any lab or EHR that implements this HL7 standard can interface with this hub.

Utilizing this Version 2 implementation guide, Intermountain and Partners Healthcare are working to make this genetic information available within the EHR, including clinical decision support, linkage to clinical genetic knowledge bases (keeping clinical interpretations on the variants up-to-date), and tools for pharmacogenomics and drug order entry. Clinicians expect to use genetic data for confirmatory diagnosis or risk for developing the disease, and determination of drug metabolism, drug efficacy, or drug toxicity.

Forming a more complete diagnostic picture for inherited conditions may require augmenting genetic data with family history data, represented by the HL7 Version 3 Pedigree model.

Source: HL7

You can get more details about EMR & its related topics from our EMR User Group.

http://www.ift.org/food-technology/newsletters/ift-weekly-newsletter/2011/january/011011.aspx#headlines1.

Background and Key Changes of the Food Safety Modernization Act

John Bode, OFW Law, kicked off the forum by providing the audience with some background on the Food Safety Modernization Act and the changes the industry can expect to see implemented by FDA immediately and in the next couple of years. Driven by the long list of major food recalls that the United States has experienced in recent years, Bode describes the Act as the most expansive change in food law since the 1938 Federal Food, Drug, and Cosmetic Act.

Bode continued by listing some of the provisions that can be expected to impact the food industry in the very near future. First, there will be increased frequency of inspections. However, as Bode explains, this is a very ambitious goal for the FDA and will be subject to the availability of appropriations. "It is difficult to imagine that FDA will get all the funding it needs," said Bode.

Another major provision of the new Act involves import certification authority. The FDA may now require certification by an accredited third-party auditor for imported foods and facilities. While this will take effect immediately, Bode noted that there is no current system in place for accreditation of third-party auditors. (Third party certification is highlighted in more detail by Robert Brackett)

Similar to current rules, the Act immediately enables the FDA to expanded records access and mandatory recall authority if the company doesn't initiate a voluntary recall.

Some provisions of the Act will take a little longer to implement and involve some major new requirements. All food facilities will soon be required to register biennially; current facility registration exists but is not kept up. In addition, a new requirement entails preventive control plans. The FDA is expected to issue regulation on this within 18 months. As Bode summarizes, registered facilities should have preventive control plans in place and these plans and all related records will be available to the FDA during inspections. There are some exemptions to this provision. Anthony Pavel discusses what will be required in the new preventive control plans.

For performance standards, the FDA plans to review and evaluate relevant health data every two years in order to determine the most significant foodborne contaminants. The agency will then issue contaminant-specific performance standards, which may include action levels.

Another provision of the Act details plans for the FDA to issue guidance and regulations to protect against intentional adulteration. The guidance, which will include model vulnerability assessment and examples of mitigation strategies and measures, is expected within the year. Foods at high risk of intentional adulteration must have preventive control plans.

A major issue with the recalls in recent years has been the speed at which the FDA has been able to trace the source of contamination. Therefore, the new Act focuses a lot on traceability. The FDA will establish a product tracing system that allows the agency to effectively track and trace food. The agency will be conducting pilot programs of the produce and processed food sectors within 180 days. As a part of the traceability efforts, the FDA will establish a list of high-risk foods and additional recordkeeping will be required for these foods. (David Acheson delves into the Act's traceability provisions).

For imported foods, the Act contains a provision of regulatory significance. The provision states that all importers must have a foreign supplier verification program in place, stating that the food complies with FDA requirements. Once the regulations are in place, approximately in two years, companies offering food for import without a compliant verification program will be subject to injunction and criminal prosecution.

Overall, Bode explained that the Food Safety Modernization Act enables the FDA sweeping new enforcement authorities, including suspension of company registration, mandatory recalls, and broader access to records. While many details of the legislation have yet to be worked out, and there is not a specific timeline for promulgating regulations, Bode expects the Act to be "substantially implemented in three years."