Laboratory-Clinical Communications
LCC Profile

A new component of the
IHE Laboratory Technical Framework

Kickoff Teleconference

1/27/2012

The Problem

- The traditional order-result paradigm does not include clinically-important workflow related to ordering and resulting
  - Recommending and accepting order modification
  - Requests and responses for verification, clarification, interpretation, to fully meet clinical need (fulfillment)
- Occur on an ad hoc basis outside of systems, limiting documentation, decision support, process standardization, quality improvement
- Clinical lab context, but general applicability

http://wiki.ihe.net/index.php?title=LCC_Long_Proposal_-_wiki

LCC Long Proposal - wiki

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Proposed Work Item: Laboratory-Clinical Communications (LCC)

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Version: 1.0
Domain: Clinical Laboratory

Summary

The communication and resolution of order modification, result verification, and result interpretation problems is an integral part of quality laboratory service but it is currently managed outside of information systems. Communications can be delayed or lost and correction of the immediate and systemic problems indicated by these communications is time consuming and error prone. This new profile will enable rapid, standardized, automated capture of and response to sample problems or result questions, and will allow this information to be logged, tracked, and included in QA studies and process improvement projects.

Goals

The LCC Profile works in conjunction with the Lab Testing Workflow (LTW) Profile to support:

- ✦Within-system communication and documentation of order change recommendations
- ✦Within-system communication and documentation of result verification/interpretation requests
- ✧Better integration of laboratorians and pathologists into the patient care team
- ✧Better monitoring of the clinical performance of tests with new opportunities for process improvement

Rapid deployment (HL7 v. 2.x)

Use Cases

- Order modification
  - Specimen problems
  - Reference laboratory problems
  - Laboratory-based decision support
  - Time-out of “future orders”
- Order fulfillment (post-result actions)
  - Results inconsistent with clinical picture (e.g., verification request)
  - Test interpretation request
  - Incorrect testing or process problems
  - Flagging results of interest for follow up or research

Order modification prior to testing

1. A problem in transport damages some of a set of blood specimens. The tubes allow some but not all of the ordered tests to be completed, but the selection of the most useful combination depends on the patient's clinical status. An LCC message is returned to the ordering EHR that provides notice of the loss of specimen and presents alternatives for testing on the available specimens. The clinician chooses the most useful combination of tests to run immediately and schedules a follow up blood draw to provide specimens for the remaining tests. The information is returned to the LIS where the initial order is amended, the follow up blood draw is scheduled as a new procedure, and the problem and its resolution are captured into a QA database.
2. Specimens are drawn by a local clinical laboratory and shipped to a reference laboratory, with a testing order transmitted via their reference laboratory interface. On arrival it is found that the specimen is of inadequate volume. An LCC message is returned to the local laboratory via the interface that indicates the problem, the tests that can be carried out on the available specimen, and the amount and type of additional specimen needed. If appropriate specimens are available, the local lab can elect to ship them immediately to complete the original order. Otherwise, the laboratory can pass the message back to the ordering EHR for amendment of the original order and/or additional sampling.
3. A physician seeing a patient for hyperlipidemia writes a future order for a lipid panel in 4 months and asks the patient to return in 6 months for follow up. When the patient has not visited the lab by 5 months, the order expires and an LCC message is returned to the physician's EMR indicating no-show expiration and allowing extension of the order with notification to the patient, or cancellation of the order. *Note: It often matters clinically whether a test has expired due to a no-show or has been canceled for other reasons. Current systems do not do a good job of providing this information to clinicians and queuing up their likely responses.*
4. In the not-too-distant future, a physician orders a set of diagnostic tests on a patient. An advanced decision support system running at the laboratory determines that the information value provided by one or more of the tests is limited, based on patient demographics, existing test results, information from the literature, and continuously-updated local disease incidence statistics. An LCC message is returned recommending cancellation of the limited value test(s) and potentially suggesting alternative tests with greater value. *Note: This scenario is a bit futuristic, but more limited decision support related to test utilization is possible now. Decision support for test ordering is currently managed in the ordering system (the EHR) but in settings where a lab supports multiple small ambulatory EHRs, maintenance of sophisticated decision support rules individually in those EHRs will be difficult. Future standardization of decision support rule format will help, but certain forms of sophisticated or laboratory-specific decision support are best managed in the LIS. Currently there is no pathway for LIS-based decision support to be communicated back to ordering physicians using EHR. LCC messages will provide this pathway.*

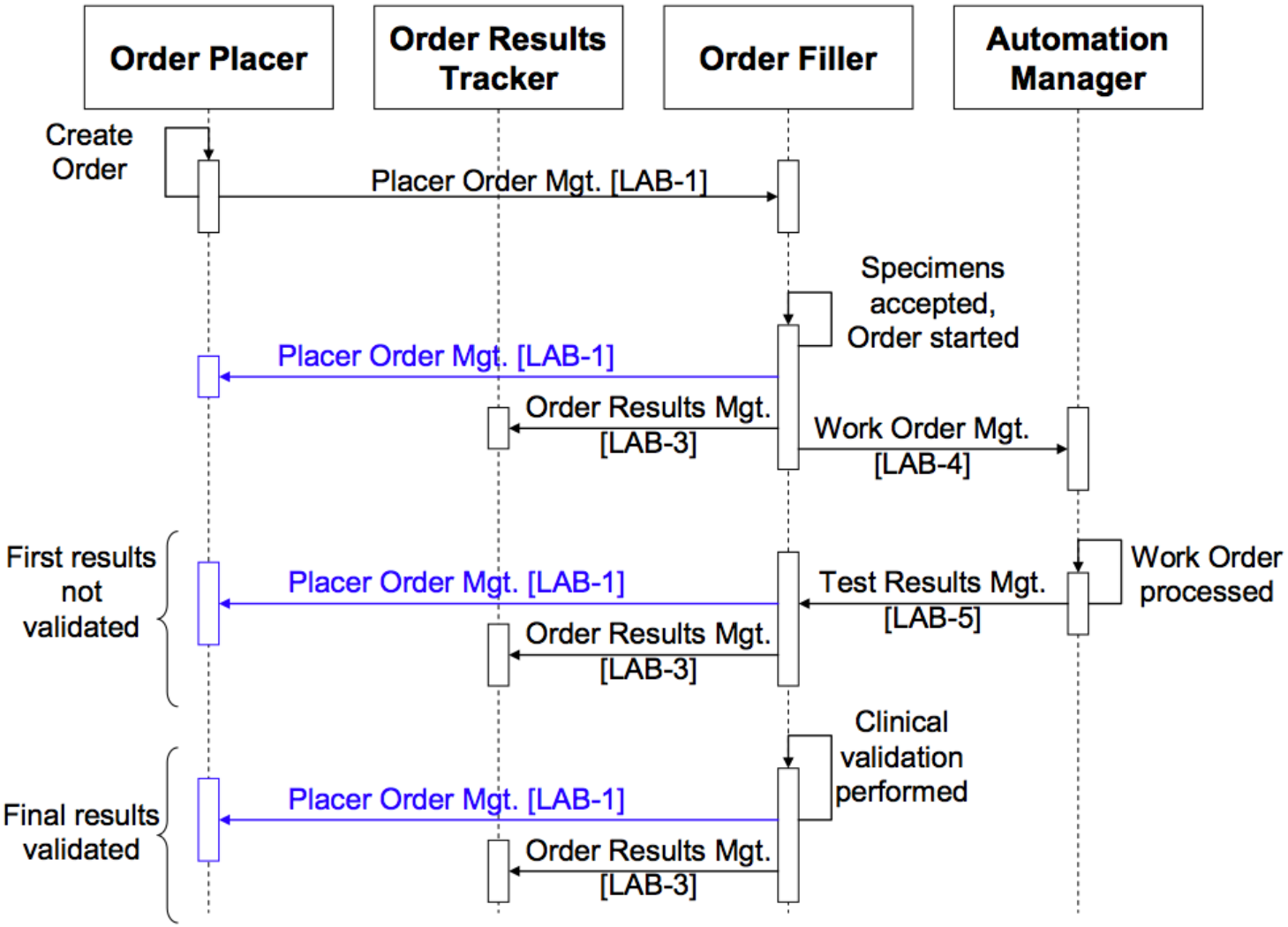
Order fulfillment (post-result action to fully meet the individual and collective clinical need)

1. A patient in the ER with substernal chest pain and a non-diagnostic EKG initially has a cardiac Troponin I (cTnI) below the level of detection but the second value is elevated, prompting the patient's admission to the acute cardiology service. The third cTnI value is again undetectable. Verification of the previous elevated value and the current normal value are requested through the EHR via an LCC message, yielding a corrected result of "undetectable" for the previously elevated specimen. The patient is discharged without catheterization. Routine monitoring of verification requests reveal an elevated number for cTnI since a new test formulation was deployed several months previously. Reports of these results to the test vendor from multiple sites lead to reformulation of the assay with improved performance. *Note: This scenario is derived from actual events and is representative of multiple examples of feedback to test kit vendors from practical use settings. Such test performance monitoring is currently done manually with significant effort, cost, and delay in reporting.*
2. A patient with joint pain, fever, and sudden onset deep venous thrombosis showed an elevated PT and PTT with otherwise normal coagulation tests. An interpretation was requested of the PT and PTT results from the EHR via an LCC message. The interpretation added as an addendum to the test panel indicated that the results were consistent with a lupus anticoagulant and recommended the appropriate evaluation strategy.
3. An endocrine service that performed IGF-1 testing for pituitary evaluation found occasional instances where mildly-to-moderately elevated levels of IGF-1 occurred in patients who did not have pituitary disease. This discrepancy between lab and clinical findings was reported on an ongoing basis when it occurred, with a brief LCC message that could be sent from the EHR to the LIS with only a couple of clicks to note the lack of clinical correlation. No technical problems with the test were found locally, but ongoing statistical analysis of these responses across multiple tests revealed a higher-than-expected rate for IGF-1 and this was reported to the test vendor. Similar performance monitoring reports from multiple locations led the vendor to review the use of a reference range established in Scandinavian populations with US patients, and design a reference range study for the US. *Note: This scenario is derived from actual events. A standard method to simply and easily capture clinical assessment of test performance would allow automated performance monitoring and much faster reporting and response to performance issues than is currently possible. Ultimately, this capability would promote performance improvement at both the local laboratory and national vendor levels.*
4. There is a local quality or process problem in testing, for example, the wrong test was done, the turnaround time was excessive, the interaction with the patient or ordering physician was problematic, etc. A problem flag with a coded and/or free text explanation is easily attached to the result for quality assurance followup and reporting. *Note: this capability allows development of databases that directly support and monitor local laboratory performance improvement. The ability to flag a result quickly for a quality issue would encourage reporting of problems, as opposed to the more typical incident reports which are handled externally and are awkward to manage within the clinical workflow.*
5. An endocrinologist with a busy practice sends testing to an academic center in a nearby city, and collaborates with faculty there in clinical research studies. When a patient displays an interesting result suggesting benefit from future research follow up, or inclusion in a clinical trial, the clinician can quickly flag the result with a pre-defined code that allows it to be retrieved easily in subsequent searches. The academic center scans their results on a weekly basis and takes appropriate action for flagged results (e.g., inclusion in registries or follow up for trial participation). *Note: this repurposes the fulfillment mechanism to allow arbitrary flagging of results.*

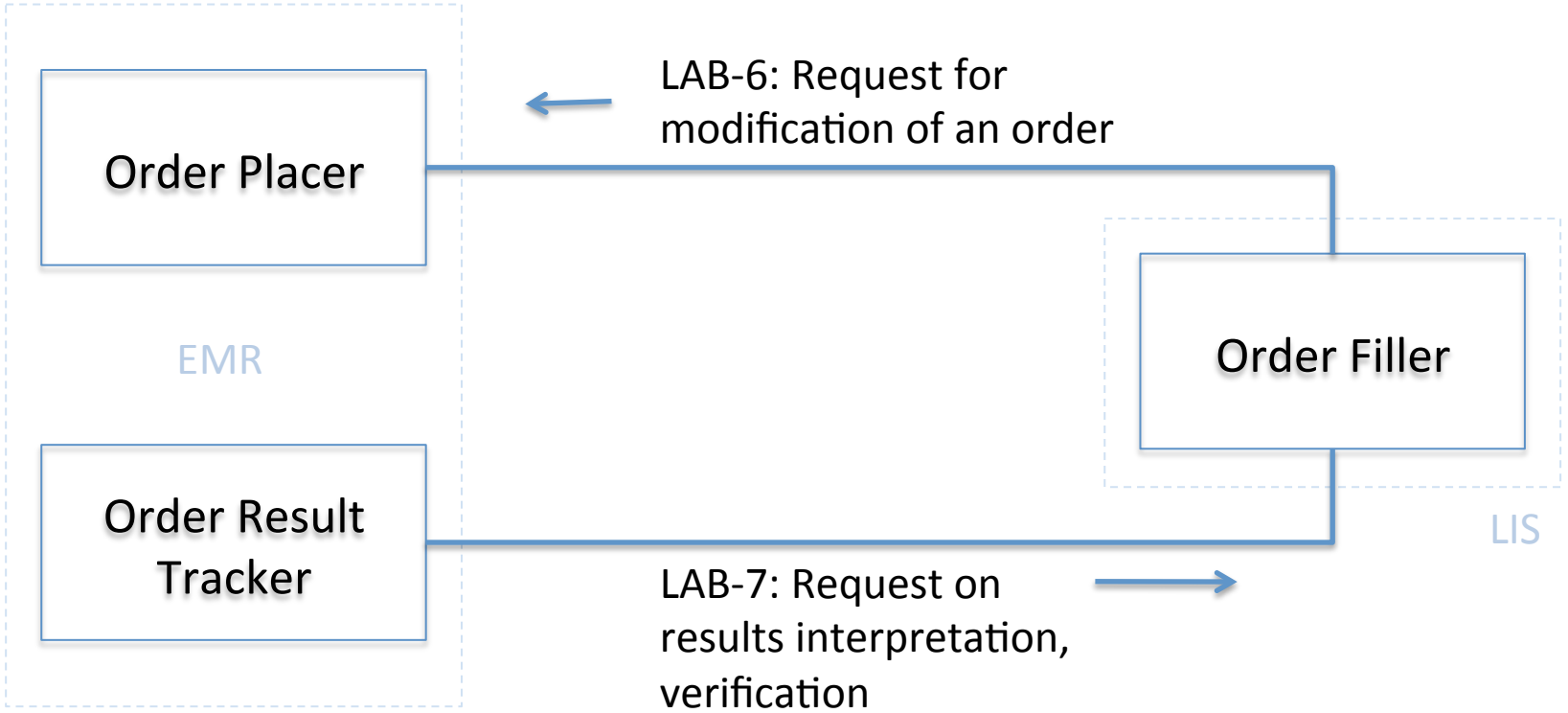
Participants

- Committed so far… (~19)
  - IHE Standards Organization
  - Epic
  - Cerner
  - Sunquest
  - Elekta
  - Pacific Knowledge Systems
  - ARUP
  - CAP
  - Others? (MGH, GE, Eclipsys, Siemens…)

Current LTW Transaction Sequence



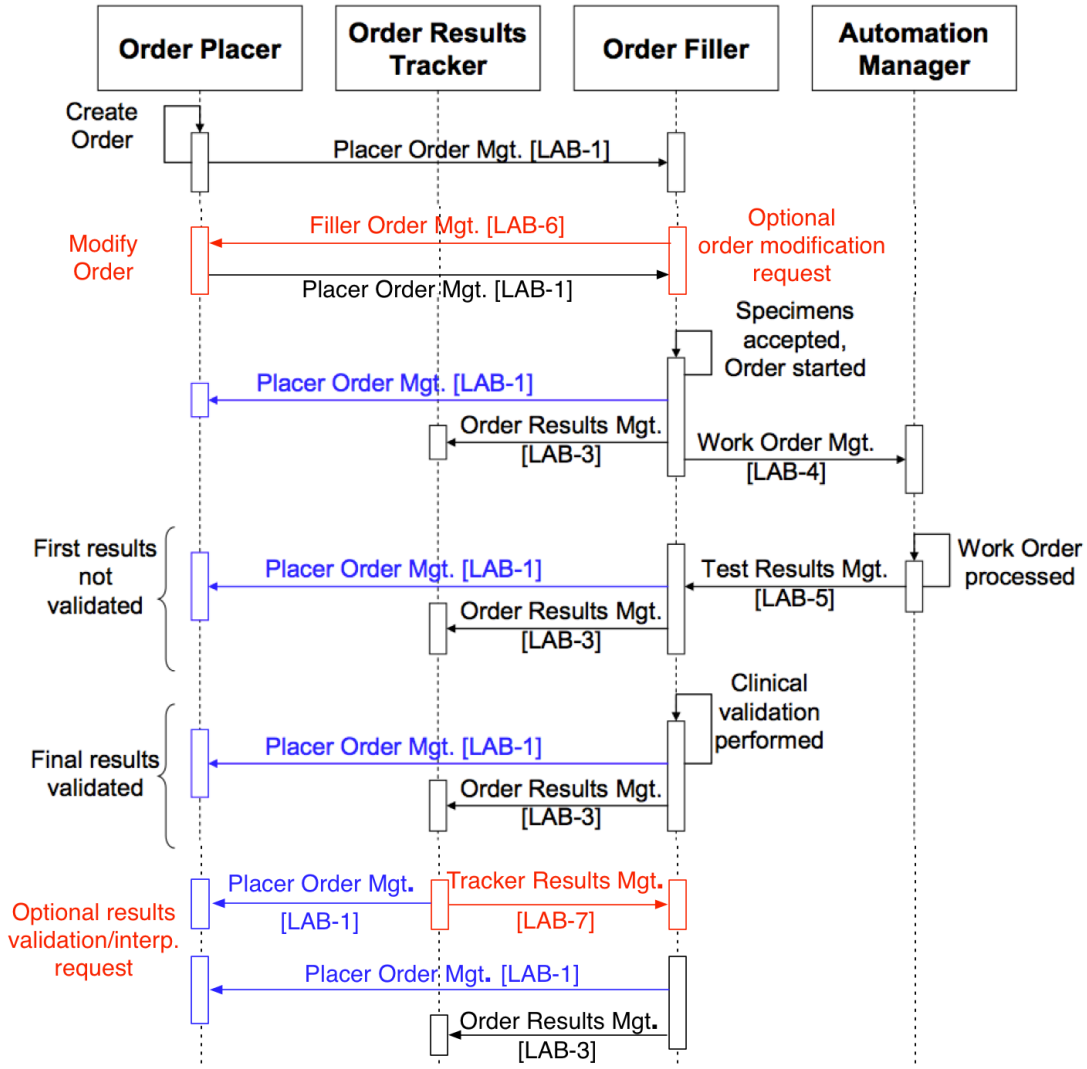
New transactions proposed for LCC



Shown in red on the next slide

Tentative LCC Implementation

(additions shown in red)



LCC Development Task Overview

Phase I

- Use case completion
- Extraction of actors, data elements, and transaction patterns from use cases
- Preliminary mapping to HL7 data elements and messages

- *Evaluate HL7 dependencies and establish Phase II timeline*
  - HL7 development if necessary

Phase II

- Complete definition of LCC messages and data
- Profile document
- Initial balloting Fall 2012 or 2013
- Initial Connectathon implementation Winter 2013 or 2014

HL7 Dependencies Evaluation

- Starting point: order modification in HL7 2.51
  - v. 2.51 chapter 4, OML 21
  - XO or XX control codes; reverse direction
- Starting point: result verification in HL7 2.51
  - v. 2.51 chapter 5, follow up order
  - Special action code, linkage to previous order
  - Possible defined vocabulary for request reason
- If new definitions, data elements, or messages
  - Recommendations to HL7 O&O for v. 2.9
  - "Pre-adoption" of 2.9 elements into 2.51 or 2.71
- Availability of HL7 specifications to LCC workgroup members

Logistics

- IHE Lab Domain Wiki
  - http://wiki.ihe.net/index.php?title=Laboratory
  - http://wiki.ihe.net/index.php?title=Laboratory_Technical_Committee
  - http://wiki.ihe.net/index.php?title=LCC_Long_Proposal_-_wiki
  - http://www.ihe.net/Technical_Framework/index.cfm#laboratory
- IHE Lab Google Group
  - http://groups.google.com/group/ihe-laboratory-committee
- IHE Lab Conference Calls
  - Tuesdays, 9 – 10 am EST, every other week
  - Next is Jan 31 (next Tues)
- Staff
  - Mary Kennedy, CAP, mkenne@cap.org

Tasks

- Initial task list
  - Use case validation
  - HL7 2.51 message review
    - Order modification
    - Results verification
- Initial task timing
  - Use case validation Feb 14
  - Preliminary assessment of HL7 2.51 applicability Feb 28

Discussion

- Assessment of tasks?
- Work strategy
  - Asynch communications
  - Teleconferences
  - Minutes
- Timeline
- Task assignments
- Follow up at 1/31 IHE conference call