

Questions from the HIT Policy Committee / Information Exchange Workgroup:

General Questions:

1. What are the technology impediments to the electronic exchange of lab data?

1. Lack of standardization. Currently there is virtually no standardization of lab ordering and results reporting messages. Most labs use variations of HL7 (typically version 2.2 or 2.3), but given the HL7 v2 framework there is incredible variability in how HL7 messages can be used for delivering results. A highly constrained HL7 message such as ELINCS is needed to remove this variation and the guess-work that accompanies it when configuring sending (lab) and receiving (electronic health record – EHR) systems.

There is also virtually no standardization of lab test nomenclature – a “dictionary” that standardizes and codes the lab tests being conducted. Virtually all lab information systems employ their own proprietary lab test codes. This requires receiving EHR systems to “map” these proprietary codes to their own internal codes. The industry-wide adoption of a common coding scheme such as LOINC would eliminate the need of this mapping activity which requires considerable expertise. Lab information system and instrument vendors should adopt LOINC; this could be done by requiring labs and EHRs to adopt LOINC through the national certification process and CLIA. Labs and providers would then be incentivized to include this requirement in their procurement processes; creating the necessary market-driven incentive to adopt them.

2. Lab compendiums and patient identity. There is currently no standardization of lab order sets or compendiums for lab orders. A standardized lab compendium would expedite lab interface implementation by removing guess work from lab orders. A common methodology for identifying patient identity would further remove much of the patient-identity matching process.

2. What are the business case impediments to the electronic exchange of lab data?

The cost of supporting interfaces given the lack of standardization mentioned above is significant. The typical lab interface can take as long as three months *on average* to implement. This is a result of both the lack of standardization and CLIA requirements (see below). This cost is typically passed on to the provider adopting and implementing an EHR, often by the EHR vendor; the *typical* cost of each lab interface is \$5,000. If

the provider represents a big enough book of business for the lab the lab may actually pay the provider's EHR vendor fee. If the provider represents a small book of business for the lab then the lab may refuse to support an interface for that provider as the cost to the lab to support that interface exceeds their expected proceeds from building and maintaining that interface. This happens frequently for providers where a subset of their panel has insurance through a payer that has an exclusive lab contract with the provider's secondary or tertiary lab vendor. As a result, the provider will receive faxes for these patients from the labs and will develop a manual process for incorporating those results into the EHR.

3. What are the operational impediments to the electronic exchange of lab data?

Given the lack of standardization of results, test codes and patient identity, considerable manual effort is required to implement each interface. If a patient's identity cannot be correlated, then a manual process (requiring a person to intervene and confirm a patient's identity) is needed before a result can be filed into the EHR. Similarly, given the lack of a highly-constrained lab result message or a standardized compendium or test codes, the negotiation between the EHR vendor and the lab to ensure that the right lab for the right patient with the right codes is sent to the right provider can take months to complete.

4. What are the regulatory impediments to the electronic exchange of lab data?

Much of the three month implementation process described above occurs as a result of Clinical Laboratory Improvement Amendments or CLIA regulations. CLIA regulations put the burden on laboratories, and make them accountable for the way that EHRs display lab results to physicians. Under CLIA, labs must ensure that the right lab tests and results are sent to the right provider, for the right patient. This is appropriate. However, CLIA also puts the burden on labs to verify that the EHRs are configured to display lab results correctly. This may require on-site verification by lab personnel that the test is displayed correctly. Labs must therefore make a business decision whether to support physician customers and must do so based on the arithmetic that they bear considerable costs for each interface. For this reason, labs may decide it does not make business sense for them to send electronic results to physicians who do not represent enough business

5. What is the low-hanging fruit for improving electronic exchange of lab data?

(1) Use CLIA, national certification and meaningful use regulations to require that a highly constrained HL7 result message and implementation guide such as ELINCS be adopted and used, and require that EHR vendors display the lab results in a CLIA compliant way.

(2) Develop and support a highly constrained HL7 message order

(3) Require the use of LOINC

(4) Modify CLIA regulations to require labs to verify whether or not the receiving EHR is federally certified and require labs to send results using the same national standards that EHR vendors are certified against

6. What's a priority to facilitate easier/broader electronic exchange of lab data, even if not immediately actionable?

7. What best practices would you recommend in this area?

Engage in an open, inclusive and transparent process to implement new regulations as suggested above in a manner that will allow the industry to comply with these standards in a timely fashion. The process must take into account the current limitations of the lab industry, including a considerable lack of resources and expertise, mostly in the small lab and hospital outreach lab segments. The approach should be incremental, and not require the industry to adopt standards and practices that are far beyond their grasp. Finally there should be a national clearinghouse of best practices to support providers, labs and vendors as this standardization takes place.

8. What work-arounds for these impediments have you experienced/designed/observed?

Most labs and EHR vendors have their own "libraries" that they use once they've developed interfaces with each other (e.g., once "Highland Labs" has implemented an interface to "MyEHR System" for a practice, both the lab and vendor will store that interface in a library). That helps the next time these two entities interface with each other. But for every system upgrade (EHR or lab) those interfaces need to be upgraded as well. Labs and EHR vendors may have hundreds or even thousands of interfaces in their libraries, each on requiring maintenance and updating for every new version that is released by any of their trading partners.

Specific Questions:

9. Has your State's definition of "authorized person" limited the ability of health care entities to exchange lab data electronically?

10. How do you, your laboratory or EHR vendor view the requirements set forth in 42 C.F.R. § 493.1291 (Requirement that the test results and other patient-specific data are accurately and reliably sent from the point of data entry to final report destination, in a timely manner)? For example, technical method or visual "eye-ball" inspection of every terminal/interface in an installation to ensure that data is displayed correctly.

11. How do you, your vendor, or State interpret "final report destination?" Does this interpretation hinder the electronic exchange of lab data?

12. Do you believe that the adoption of a universal compendium/dictionary will reduce costs related to the implementation of lab interfaces and improve electronic exchange?

Yes, this would expedite the interface implementation process considerably and remove guess work and likely improve compliance with CLIA. The compendium would have to be both adopted and used to be effective and all levers (CLIA, meaningful use and national EHR certification) should be considered to ensure adoption and use of a universal compendium

13. Who is best suited to maintain a universal compendium?

This should be determined through an open process and the entity must be trusted by the lab, EHR and provider industry and government.

14. What standards, if any, would you recommend for the electronic transmission of lab data?

- ELINCS (for clinical reporting of patient-specific lab results)
- CALINX (retrospective batch reporting of lab results)
- LOINC (for standardization of lab test codes)

15. How do you ensure lab data is transmitted securely and confidentially?

16. What are the obstacles preventing patients from receiving copies of their lab data?