

Questions from the HIT Policy Committee / Information Exchange Workgroup:

General Questions:

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

-The lack of highly constrained implementation guides that specify both the structure and coding of lab data with a minimum of optionality. Optionality results in heterogeneity of interface implementations across vendors and lab-service providers. The heterogeneity necessitates more customization and implementation work when any specific lab and an EHR endeavor to interface. This work raises the costs of interfacing for all parties involved, often to a prohibitive degree (the smallest physician practices and hospital laboratories that provide “outreach” lab services are especially sensitive to these costs).

-To a lesser degree, the lack of widely supported “transport-level” standards, which would enable labs and EHRs to implement a single method for securely transmitting and receiving lab data, regardless of trading partner. Again, such standardization would reduce the effort and cost required to implement customized solutions (VPN vs. secure FTP vs. web services) for different trading partners.

-The general absence of support by L.I.S. vendors and laboratory instrument vendors for standard test coding (specifically, LOINC codes) within their products. This gap necessitates that reference labs and hospital labs who wish to use these codes must themselves perform the mapping between LOINC codes and the proprietary codes used by their L.I.S.’s and/or lab instruments. The process of mapping a lab’s entire test catalogue (and subsequently maintaining the mappings) entails significant personnel time and/or costs, which smaller labs are often reluctant to undertake. “Built-in” LOINC mapping in L.I.S.’s and instruments would greatly reduce this mapping and maintenance burden and constitute a much more efficient solution than each customer of an L.I.S. or instrument vendor performing substantially the same mappings locally.

-For purposes of shared clinical data repositories (i.e., “RHIOs” or “HIEs”), the challenge of correctly matching patient identities in the lab data from one information source with those in another remains a vexing problem. This is less of a problem in “point-to-point” transactions involving lab-test ordering and results reporting. In these cases, locally unique identifiers (i.e., those that are unique to a single enterprise or information system) are typically sufficient for reliably associating test results with the correct patient record. This is because the order typically emanates from and the result is transmitted to the same system or enterprise. (However, even in this situation, patient-identity handling cannot be taken for granted – see response to Question #3).

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

- Currently, the cost to labs to implement, test, and maintain a customized interface for a specific physician practice may exceed the benefits to the lab of building that electronic interface if the practice’s lab-testing volume is relatively small. Because a lab must expend roughly the same

effort to implement a lab interface with a large physician practice as with a small practice, larger practices with greater testing volume will typically receive priority. When a lab's resources for interface development are limited (almost universally the case), smaller practices may never achieve a sufficiently high priority (from the lab's perspective) to get an interface. Because labs that perform ambulatory testing will not receive monetary incentives to comply with "meaningful use" criteria, they will be motivated solely by the relative importance of their business relationships with various outpatient practices, which often disadvantages smaller practices. This issue is a greater impediment with respect to large reference labs than hospital labs, because hospitals usually have multi-dimensional relationships with community physicians that extend beyond lab testing (e.g., patient referrals).

- Certain EHR vendors charge labs for building and supporting lab interfaces to their physician clients (sometimes also charging the physician practices as well). When the charges are commensurate with the EHR vendors' costs to implement and maintain each interface, these charges are justified. However, in certain cases, the charges appear to be part of the vendor's revenue model, such that even successful standardization efforts that reduce the level-of-effort to implement lab interfaces may not result in a reduction of the charges to labs. Competitive dynamics may eventually address this when the meaningful use criteria strongly incentivize physician practices to acquire electronic lab interfaces (and therefore favor vendors with whom the practices' labs are more apt to interface). On the other hand, the higher demand for electronic lab interfaces under "meaningful use" may prompt certain EHR vendors to charge even higher fees.

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

- When there is not adequate coordination between the ordering process and the result-reporting process, results may not automatically match to existing orders or existing patients in an EHR. This can happen, for example, when the patient-identifying information placed on lab orders does not exactly match the information in the EHR or is not recorded and echoed faithfully by the lab. In these cases, the results are considered "unsolicited", cannot be automatically filed by the receiving EHR system, and must often be manually associated with the correct patient and/or order. This creates both additional work load for practice staff and increased potential for errors.

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

- Certain reference labs interpret the CLIA regulations to require that they review and validate the specific manner in which an EHR processes and display the electronic lab results sent to the EHR. This creates an additional step and additional cost on the part of the lab for the interface implementation and testing process, which, all other things being equal, reduces the number of interfaces that labs are willing or able to support (again, smaller practices may be particularly disadvantaged due to their lower testing volume). It may be useful to explore regulatory changes that achieve the safety and reliability goals of the CLIA regulations in a manner that is more efficient (for example, by requiring that CLIA-compliant processing and display of lab results be an intrinsic feature of "certified" EHRs, thereby obviating the need for labs to verify this on a practice-by-practice level).

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

- Develop and promote highly constrained implementation guides for lab ordering and result reporting that meet the immediate practical needs of both labs and EHRs and that can be

implemented in the near term by these stakeholders. Eschew over-engineered standards or monolithic suites of standards that, while fully standardizing entire use cases, cannot achieve broad adoption among vendors and provider organizations (both large and small) in an 18-24 month time frame. Anything that takes > 24 months to achieve broad adoption is high-hanging fruit...

- Incentivize or compel the manufacturers of L.I.S's and laboratory instruments to natively support LOINC codes within their products (for example, by making such coding part of CMS payment requirements).

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

- Higher-hanging fruit: specification of transport-level standards (perhaps based on web-services protocols) as well as shared repositories of directory/registry information and compatible message-routing capabilities that create an infrastructure to send/receive lab data to trading partners in a uniform way, regardless of the type or size or location of the information systems involved.

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

- All standardization activity should allow sufficient time to engage all of the relevant stakeholders and to thoughtfully consider the requirements and specifications for interoperability in a manner that will ensure near to medium-term adoption by the mainstream of the healthcare industry. There must be a pro-active effort to seek out and engage all manner of stakeholders during the standards-development process to ensure broad adoption of the standards that result. There must be sufficient time for otherwise busy stakeholders to adequately review, comment upon, and test the proposed standards.
- Sufficient implementations of and real-world use of proposed lab-exchange standards must precede their designation as "national standards," especially if their use will be mandatory or tied to monetary incentives.

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

- Certain EHR vendors and reference labs will negotiate and implement pair-wise data-exchange solutions. This obviously helps when a required interface involves those and only those parties. However, not infrequently, physician practices work with multiple labs or a single lab must interface to a variety of EHRs, so this is but a partial solution.
- Certain EHR vendors and labs have adopted highly-constrained implementation guides that are not among those designated by the federal health standards activity (for example, ELINCS), but which enable relatively rapid implementation and which support their key business and clinical requirements.

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, no doubt. However, the key word is “adoption.” The design and pace of standardization in this area must accommodate the capabilities of reference labs, hospital labs, and EHR vendors, both large and small.

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

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)

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?