

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 standardization is one major impediment. Not all laboratories have LOINC coded their results. There is no standard compendium or even standard naming convention for orders. Insurance files are specific to the practices, and vary widely. Laboratories also vary in how they identify providers as some use the UPIN while others use the newer NPI.

Furthermore, there is no standard or organized way to update these compendiums and files. Labs typically send a fax to the provider to update their compendium, but busy physicians, particularly at small practices find it difficult to perform the technical updates, especially for multiple labs.

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

While hospitals and larger practices usually provide significant business for commercial laboratories, small practices often do not order enough lab tests to justify the implementation of a laboratory interface. While costs quoted to us by various stakeholders have varied, generally labs must pay between \$2500 to \$5000 per interface either for their own development or to a vendor, not including maintenance costs. Small practices often don't meet the lab requirements for return on investment and therefore they are reluctant to implement labs in these environments.

In addition, practices usually require more than one interface due to patient insurance requirements as well as clinical reasons and patient preference. This reduces further the share of lab orders per laboratory. It would appear from our experience that the burden for creating and maintaining lab interfaces is especially difficult for smaller lab companies.

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

Practices do not have the "bandwidth" to perform insurance file and lab compendium mapping on an ongoing bases. When lab compendiums and insurance files are not updated they result in errors, time delays and at times "unreconciled labs" or labs that are not routed to the ordering provider that need to be manually identified in the EHR and correctly sent to the ordering provider by practice clinical or office staff.

In addition, a lack of technical expertise at the practice can make it difficult to identify and address technical issues. Finally, training is necessary for the practice to use the lab interface correctly, including ensuring that the lab result is reconciled to the appropriate patient if the lab has become “unreconciled”. Training is often an issue at small practices which are usually under resourced and over-burdened.

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

The CLIA regulation that holds the laboratory responsible for the results of the lab test as they appear in the Electronic Health Record interface probably presents the greater regulatory impediment to implementing interfaces.

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

Decreasing the implementation and testing time for new implementations would greatly increase the expansion of laboratory interfaces, as presumably costs would decrease. Currently the interface implementation timeframe is between 10-14 weeks, a process that includes identifying the compendium requirements, exchanging HL7 files and spec walk thoughts, configuration, installation, training, use cast testing, functional testing, code change testing and final testing.

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

Creating and hosting a standardized compendium and insurance file would save enormous time and costs for both implementation and maintenance. This type of compendium and insurance file could be part of a shared content manager.

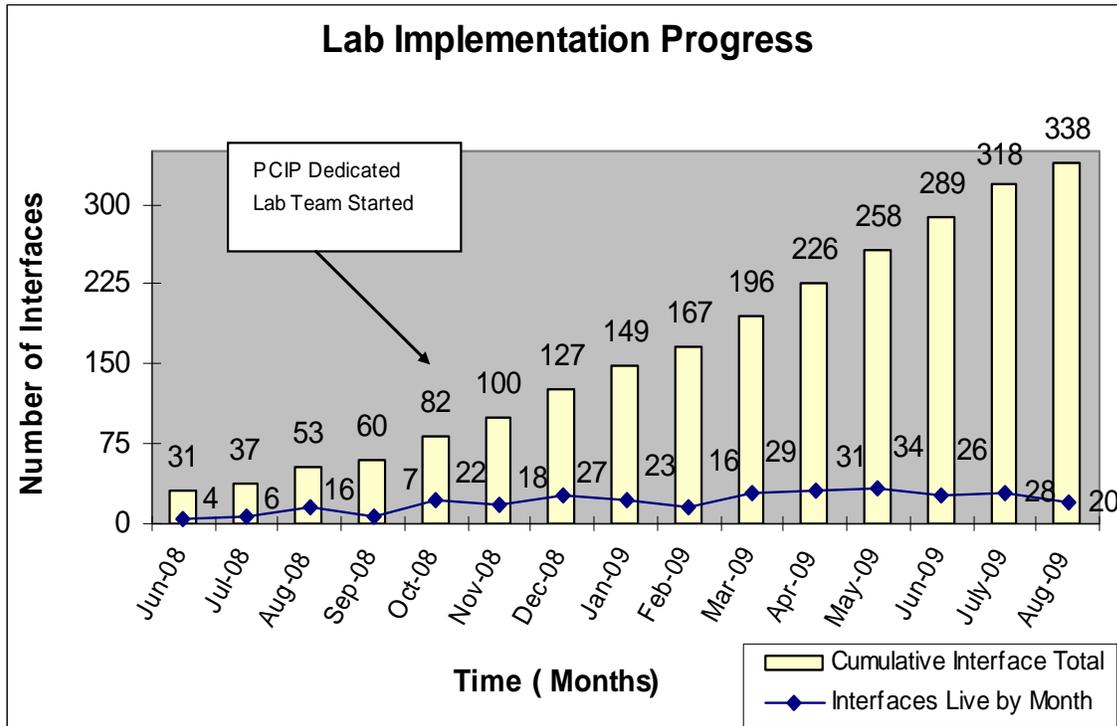
7. What best practices would you recommend in this area?

We are currently in the process of creating a shared services manager for our practices as constantly updated compendiums and insurance files is not realistic for a project our size. We believe that New York State through the development of the State Health Information Network is also contemplating similarly shared services.

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

To achieve the expansion of lab interfaces to our small practices we have addressed the problem on multiple fronts. First we advocated for our providers to ensure they would receive an interface, meeting with leadership at several commercial laboratories. Later we worked with our vendor and the laboratories to prioritize interface requests. We allocated staff to monitor each lab interface implementation, working with practices to ensure they were receptive to the interface process and sharing best practices for workflows. We also have provided technical assistance to our smaller practices as well as working extensively to facilitate troubleshooting

during difficult implementations for our larger, more complex practices. We currently have 354 interfaces live for 276 practices representing 1557 providers:



Specific Questions:

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

New York State is one of only two states that are CLIA waived and therefore are regulated under Wadsworth Laboratory of the New York State Department of Health, which may have similar regulations. I do not have personal knowledge that the CLIA regulation limits the exchange of lab data electronically but it could be one factor in the amount of testing and design required to implement lab interfaces.

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.

CLIA as currently constructed, holds laboratories responsible for the format of the result viewed by the clinician. In an electronic context, laboratories should be held responsible only for verified delivery of the standardized message content to a clinical information system. The format for display of laboratory results in the user interface is largely if not totally under the control of the EHR vendor. It may be appropriate for CLIA regulations to also require validation and certification of how electronic health record products render the information received by clinicians. For the same reason, CLIA requires laboratories to test and validate each individual interface, a laborious and time consuming process, which, in many cases, is redundant, since a single “master interface” connecting laboratories and EHR vendors can ensure standardized and consistent delivery of laboratory information.

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

This interpretation hinders the implementation of lab interfaces because it holds the laboratory responsible for the final format and view of the lab results in the EHR. The interface is largely under the control of the EHR vendor, and this requirement has been interpreted as a responsibility for the labs and is one of the reasons for the extensive and costly testing of lab interfaces.

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, the current system of individual compendiums and insurance files is costly, difficult and does not scale in any way for large numbers of providers using an EHR. The current system leverages little of the available technology to scale adoption or accuracy of lab data.

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

A universal compendium can be part of a shared content manager, which would include a central lab compendium, insurance file and other information and should be hosted and maintained at the state level as states regulate insurers and providers as well as other health care entities. Appropriate organizations could be a State's Department of Health or Department of Insurance although other governmental entities would be appropriate as well. The important issue is that the information is always current and is pushed out to providers through the EHR.

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

LOINC coding for results should be mandatory. There should also be some standardization around orders, even if there is some type of naming convention. Similarly, most if not all insurances have different products with different names and identifiers. A standard naming convention or identifier would reduce the lab interface development and testing time. Finally, providers are not identified in the same way by labs, some use the UPIN identifier while others use the newer NPI.

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

Throughout the testing process, the lab and the practice work to ensure that the lab results are populated in the EHR properly. Much of the security and privacy on the provider side are dependent upon proper role or user based access being configured in the EHR. This ensures that staff that have a need to access lab data based upon their job duties have access while restricting the access of staff that do not have such a need. Training on privacy and security for the practice is also imperative, and we have dedicated staff that visit the practices and discuss access controls, network security, encryption and other means of protecting patient data, including lab orders and results. We also help the practices develop their own policies and procedures based upon guidelines we provide. Finally we provide technical assistance to configure the EHR to appropriate protect patient data including lab data.

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

The CLIA Regulations require that the lab results are specifically provided only to "an authorized person" New York State is CLIA waived, and under NYS regulations (CLEP) the law does not allow a layperson to receive lab results unless the lab result was 1. authorized for release by the ordering provider 2. is an RH test of a blood type test.