

Questions from the HIT Policy Committee / Information Exchange Workgroup:

General Questions:

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

- Multiple versions of standards and individual interpretations by providers and EHR vendors in each version of the standards require substantial IT resource and creates burden for implementation and maintenance of the systems.
 - Different versions of HL7 – for example - HL7 v2.3, v2.3.1, v2.4, v2.5.1, v3.0 etc
 - Individual interpretations of each version - Functionality differs by vendor, for example, Micro results are discrete for some vendors and non-discrete for others
- Given the absence of standard patient identifier, EHR vendors and software systems are forced to use varying approaches and criteria for matching patients. As a result not all pertinent data for a patient can be aggregated into the unified patient's medical record within a system implementation for physician office – much less across a community.
- With some exceptions, the prevailing method of integration can be described as a “custom point-to-point” integration offering very little opportunities for efficiencies in the form of a repeatable process. This has changed to a certain extent in recent years with standardization and certification programs led by certain laboratories; however, these certification programs are not typically standardized across multiple laboratories. Additionally, organizations such as HITSP and ELINCS offer differing implementation guides of existing or prevailing standards.
- Efforts for new standards tend to be limited by the lowest common denominator of current prevailing implementations. For example, Patient Name has a HL7 field length of 250 characters; however, when the data is exchanged through multiple systems with varied field length constraints, the end output will only be as long as the shortest field length in the chain of systems.
- Because of multiple handoffs between systems and stakeholders involved in lab transaction connectivity, it is often not obvious who “owns” a service issue when a failure occurs – which can result in overly long disruptions in service with potential ramifications for patient care.
- Most electronic interchange (HIE) efforts to date have been limited to lab result transactions. Bi-directional interfaces, have not been widely implemented – and even when implemented rarely include the most basic set of lab-focused requirements – operations and otherwise – that are needed to support a successful transaction. The effect is a general lack of laboratory knowledge and domain expertise of the non-laboratory stakeholders, which only further magnifies the problem.

- A segment of the laboratory stakeholder community continues to utilize legacy dial-up connectivity with limited bandwidth that inhibits the parties' ability to transmit/receive large amounts of data in an acceptable amount of time. In addition, rural areas often have to rely on satellite-based connectivity which offers its own unique challenges.

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

- EHR vendors and the growing constituency of HIEs (Health Information Exchanges) and other organized health care exchange systems often expect laboratories to pay for the license and the cost of implementation for laboratory interfaces – whether for results transactions or bi-directional orders transactions. Given that these fees are in addition to the costs and resources laboratories must expend to support this transaction integration and exchange, there is not always a clear business justification or ROI for the laboratory, thereby creating a financial disincentive for laboratories to participate.
- In accordance with current CLIA regulations and interpretations, laboratories bear the additional cost to implement the lab interface in a timely manner and to ensure the validity of the orders and corresponding results
 - Redundant validation of interfaces due to CLIA Requirement 42 CFR 493.1291 (*“The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry **to final report destination**”*)
- EHR Vendors and HIEs currently do not have the same regulatory responsibility for accuracy and timeliness of presentation of the lab results, thus requiring extra resources on the part of laboratories to qualify or certify each individual EHR implementation.
- HIEs typically do not offer the technical capabilities that offer fault tolerant systems or fail-safe architecture necessary to guarantee the timely delivery (i.e., acceptable service levels) of the laboratory result transaction, therefore requiring laboratories to implement alternative delivery channels to ensure our compliance with the CLIA requirements for the laboratory “report of record.” This obligation results in increased cost of participation with HIEs and generally an extra burden for both the laboratory and the practitioner.
- Major laboratories have invested significantly in electronic data interchange, offering their customers a broad range of laboratory transaction capabilities that enhance the quality and efficacy of the orders and results transactions and result in greater user satisfaction. Duplicating these capabilities in HIE or EHR vendor systems is typically not a priority for HIEs or EHR vendors; however, these capabilities should be considered an integral part of the minimum functionality set needed for HIE or EHR certification.
- New standards efforts that do not take into account the practical implementation hurdles and costs (as well as a timeline for orderly implementation by all stakeholders) may have the unintended effect of increasing cost to the system as well as the stakeholders, while reducing implementation effectiveness for all.

- Practitioner offices often do not have qualified IT resources to implement or maintain the required systems, placing additional burden on the laboratories and EHR Vendors.

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

- Results may not be aggregated to patient records and may not file electronically to the EHR system or HIE if critical matching information is not provided within the lab order transaction
 - Manual orders have multiple opportunities for data entry error causing results not to be filed electronically into the patient's chart through mismatches or other errors.
- Practitioners may not have the electronic mechanism to provide accurate demographic or billing information (e.g. Results Only Interfaces)
- Practitioners / vendors may not include appropriate or accurate demographic or billing information if not requested by the vendor's system, resulting in manual rework for the laboratories.
- Practitioners expect laboratory results to automatically aggregate into patient charts, but often the EHR vendor systems are not designed to provide the appropriate or necessary clinical, demographic, or billing information needed by the laboratory to provide the results, match records with the patient's other records from other occasions, or to bill for the testing. Some of this failure is due to the lack of standard functionality for EHR applications, which, if implemented in all vendor systems would provide all of the information needed by laboratories to order, perform, report, and bill for all of their tests.
- Non-standard laboratory test compendiums as well as different implementation approaches by vendors for receiving, maintaining, and updating a laboratory's test compendium leads to operational inefficiencies and negatively impacts customer satisfaction. The American Clinical Lab Association (ACLA) is working with its members to define a set of requirements for standard formats, field definitions, and field lengths for an Electronic Delivery of the Test Compendium.
- Some of the required and often missing functionality that causes down-stream operational issues are as follows:
 - Proper capture of the performing laboratory's test code which is the key to identifying the specific laboratory's specimen collection requirements and ensuring that the physician's order is properly interpreted by the testing laboratory.
 - Ability to prompt physicians to print Advanced Beneficiary Notice for Medicare patients with identification and lab specific pricing of the limited coverage tests
 - Ability to identify limited coverage tests and tests subject to insurance company pre-authorization (which varies by insurer and by plan)
 - Ability to capture needed information including but not limited to:
 - Complete patient demographics to allow for subsequent matching and aggregation of patient data from different dates of service or different performing laboratories

- Secondary insurance capability
- Other needed billing information, such as collection time and date, necessary demographics for patient (including guarantor name and address), client, and third party billing
- Ordering physician name, account number, and address
- Referring physician name, NPI and non-physician provider's name and ID (NPP)
- Patient information required to meet specific state requirements (for example, genetic or HIV testing for NYS residents)
- Ability to generate multiple requisition types
 - Split requisitions for different specimen types (e.g., frozen and room temp)
 - Production of paper test requisition / specimen labels (and tying the two together – often through bar-codes)
- Ability to handle standing and / or scheduled orders
- Ability to input electronic third party orders
- Ability to prompt electronic verification of oral test add-ons
- As a result of not having EHR systems with the above capabilities, practitioners, at times, do not accurately or in a timely manner, provide the necessary information to the lab which causes costly operational re-work within the laboratory work-flow

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

- 42 C.F.R. § 493.1291(a) is generally interpreted as holding laboratories responsible for insuring the validity of the result report data all the way to the authorized person who ordered the test
 - ***§493.1291 Standard: Test report: (a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner.***
- When an EHR vendor changes or omits elements of the test result report provided by the laboratory before the vendor provides the report to the physician, the clinical laboratory may still be responsible for complying with the regulatory requirement pertaining to the content and format of that report, in accordance with the CLIA requirements stated above.
- When test result report information is disclosed by the practitioner to the HIE/HIO, the clinical laboratory may still be responsible for the final CLIA-compliant report, in accordance with CLIA requirements stated above.
- If a HIE/HIO or any person other than the ordering physician who ordered the test requests to receive test results from the laboratory, CLIA may not permit the laboratory to make the disclosure without valid indicia of authorization.

What is the low-hanging fruit for improving e-exchange of lab data?

- Include the lab interface as part of the EHR Core Product (initial deployment), so that EHR vendors do not have to perform a follow up action to install their lab interface, other than downloading the relevant individual laboratories' test compendia. Lab interfaces are typically positioned as phase 2 activities leading to mis-matched expectations and workflow impediments for all parties.
- Improve the proposed national standards certification criteria to ensure that the EHR Vendors have increased functionality pertinent to the lab order requirements as described above (i.e., Electronic Orders, PSC Hold, ABNs, etc.) and provide a process for requiring EHR vendors to add additional laboratory functionality in the future as a condition of certification.
 - For example, current CCHIT certification excludes the laboratory order / result interface
- Seek amendment of CLIA regulations or clarify through the CLIA Interpretative Guidelines that the results must be sent either to the client **or to the intermediary** to read as follows:
 - 42 CFR §493.1291(a) *“The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to [delete final report destination] the intended destination, or to an intermediary contractually obligated to send the results or other patient-specific data directly or through other intermediaries to the intended destination, in a timely manner.....”*
 - 42 CFR § 493.1291(f) *Test results must be released only to authorized persons, and, if applicable, the individual responsible for using the test results and the laboratory that initially requested the test. ADD to CLIA Interpretive Guidelines:*
 - *Individual responsible for using the test results means, notwithstanding any contrary State law:*
 - *Any person designated to receive the test results by the authorized person who ordered the test;*
 - *A “covered entity”, as defined in 45 C.F.R. § 160.103, that requests the test results for a use or disclosure for which patient authorization is not required under the HIPAA Privacy Regulations (45 C.F.R. Parts 160 and 164); and*
 - *A “business associate” of a covered entity, as defined in 45 C.F.R. § 160.103, that requests the test results on behalf of a covered entity for a use or disclosure for which patient authorization is not required under the HIPAA Privacy Regulations (45 C.F.R. Parts 160 and 164).*

What's a priority to facilitate easier/broader e-exchange of lab data, even if not low-hanging fruit/immediately actionable?

- Recommend that EHR vendors be responsible for ensuring CLIA compliant reports / information display to the ordering physician / authorized person as transmitted by the performing laboratory.
 - Enable certification bodies to have direct authority over EHR vendors to insure their compliance with the laboratory's regulatory requirements
- Create universal standards that are fully tested by the stakeholders, implementable at the time they are required to become effective, and are not open to different interpretation by the stakeholders.
 - Follow a process similar to the ANSI x12 835/837 Standards for insurance claims.
- Recommend EHR vendors adhere to a standard test compendium framework and format which is fully integrated into the EHR system. This would offer efficiencies to allow EHR vendors to download as many laboratory test compendia as needed by the practitioner.
- Recommend EHR vendors to download as many laboratory test compendia as the physician uses in his or her practice.
 - The compendium would include laboratory-specific features and dictionaries, such as order codes, result codes, Ask at Order Entry, laboratory specific ABNs, etc.

What best practices would you recommend in this area?

- Ability for the performing laboratory to certify a vendor interface by version and not for each individual practitioner installation, provided Vendor has regulatory responsibility for the practitioner's system compliance with all legal and regulatory requirements of the laboratory. This is necessary to meet the expected scale of demand for these interfaces over the next few years. Formalized or generally accepted versioning systems are an important ingredient in driving towards this scenario.
- Since lab interfaces are fundamental to the physician's practice and for demonstrating "meaningful use," they should be an integral part of every EHR Vendor's Core EHR product and should not be considered as an add-on module as mentioned above.
- The prevailing business practice around the assessment of interface fees to laboratories by EHR vendors must be re-evaluated. Confusion over financial responsibility for interface fees complicates the dialog between the practitioner, the EHR vendor, and the laboratory and is likely going to have a negative impact on the government's expectation to drive adoption and "meaningful use" at the expected pace. ARRA or HITECH should provide the impetus to drive his change.

What work-around for these impediments have you experienced/designed/observed?

- Some laboratories have created their own individual electronic interchange standards or procedures
 - As a result, HL7 versions / implementation guides differ between laboratories
- Some laboratories have created their own individual communication frameworks
 - For example; VPN, Webservices
- To comply with CLIA, most laboratories test or even certify interfaces, but this creates significant resource demands to adequately test individual interfaces to meet current regulatory requirements and presents challenges when vendors change their systems without notifying laboratories.

Specific Questions:

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

Yes; the ability of health care entities to exchange lab data electronically is limited by the state definition of an "authorized provider", which may differ from state to state. HIPAA does not pre-empt such state definitions.

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)? I.e. technical method or visual "eye-ball" inspection of every terminal/interface in an installation to ensure that data is displayed correctly.

A key CLIA accrediting organization, the College of American Pathologists (CAP), interprets the CLIA regulations to require that the performing laboratory verify that patient results are accurately transmitted from the point of data entry (interfaced instruments and manual input) to patient reports (both paper and electronic).

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

We interpret "final report destination" to mean the display visible to the intended recipient of lab test results sent through an electronic interface. Because the EHR vendor or HIE is the intermediary between the laboratory and the ordering physician / authorized person, the laboratory does not see the final report presented to the ordering physician / authorized person.

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?

While we do not believe that the creation or the adoption of a universal compendium is feasible or even possible due to variances in tests and test requirements among laboratories, we do support a universal and standardized test compendium framework, with standard formats, field definitions, and field lengths for the tests each laboratory offers, which would be downloaded in the standard format to any EHR vendor's system [sometimes two or three compendia if the physician uses more than one laboratory].

Who is best suited to maintain a universal compendium?

As stated above, we do not believe a universal test compendium is feasible or even possible, due to variances in tests and test requirements among laboratories. However, laboratories and EHR vendors and HIEs all could adopt and implement a universal and standardized test compendium framework, with standard formats, field definitions, and field lengths.

The standards and definitions for a universal compendium framework could be managed by HL7. The ACLA, in conjunction with their member laboratories are currently leading an effort in this regard.

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

Industry accepted transmission standards including Web Services

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

By utilizing industry accepted secure connectivity and the proper level of encryption in compliance with the HIPAA Security Rule.

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

Under HIPAA, patients can always obtain a copy of their report directly from the referring physician. To the extent that patients are not getting laboratory results, this suggests the need for education and enforcement. In some states, there are legislative or regulatory barriers if a patient wants to directly receive a copy of his/her report from the laboratory, either electronically or on paper, without authorization from their physician. Unless CLIA and HIPAA were amended to pre-empt those state requirements, laboratories would be in violation of federal and state law for non-compliance by releasing the result to the patient.