

Questions from the HIT Policy Committee / Information Exchange Workgroup:

General Questions:

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

-Connections to and from labs – Many labs cannot do internet-based communications and require point-to-point connections between clinic and lab. Such multiple connections are difficult to maintain and also prevent HIT providers from leveraging advanced internet-based technologies to improve upon the development of interfaces.

-Terminology mapping - There is not a universally adopted, consistent standard for lab codes, despite the availability of LOINC. Because each lab vendor has its own set of codes, HIT vendors must build and maintain a huge set of observation terms and cross-reference files.

-Inability to auto-compile orders upon receipt of results - Because of insufficient specificity in standards, and inconsistent implementation of standards, EMRs do not always receive the required data to match a result with an order automatically.

-Variances in HL7 - Agreement on a standard HL7 version would improve interface capabilities and subsequent error rates.

-Mechanisms for matching a patient's lab data to the EMR record – This process is time-consuming and error prone

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

-Cost of creating and maintaining a several custom interfaces.

-Error rates associated with lab interfaces – there is a high percentage of failed transmissions. As a result, practices have difficulty maintaining these interfaces, which leads to decreased usage of and trust in the lab interfaces.

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

-Inability to set up a test environment with both an HIT system and a lab system - This challenge has proven to be an impediment to successful roll-out of off-the-shelf interfaces.

-Because of workflow, not all data can be captured in EMRs – For example, working from the lab workflow, phlebotomists collect additional data at the time of specimen collection that may not be captured well in EMR systems. There is, therefore, a need for collaboration across the chain of information flow to be able to ensure all pieces of data required for successful completion of lab orders are captured.

-Challenge questions (e.g., Are you pregnant? or Are you diabetic?) - There is no consistent agreement on who captures such data and how it is shared. Agreement on standard workflows would make data exchange more efficient and manageable

-Costs associated with functionality – Such costs are an organizational impediment. Financial concerns often arise around who should bear the brunt of such costs, including data transmission and the maintenance and correction information

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

A lack of standards, see below.

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

Identifying standardized vocabulary for common laboratory orders and results. This work is currently being developed in ANSI/HITSP in response to Laboratory Orders Extension requested by the Office of the National Coordinator.

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

Accurate and timely completion of lab orders from the EMR to the lab system, with results back to the EMR, must be the top priority and the following are needed to make progress on this workflow:

-Common terminology for lab codes (e.g., an RBC is an RBC, no matter the lab with which we are interfacing)

-Advancement of communication of laboratory reports as clinical documents using XML (e.g., the ANSI/HITSP C37 Laboratory Report Specification) and sharing such documents using web services (e.g., those identified in the ANSI/HITSP Capability 127 Communicate Laboratory Results Document). The exchange of clinical laboratory results as clinical documents will address issues of persistence and stewardship of results that cannot be achieved in the current messaging environment.

What best practices would you recommend in this area?

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

Use of cross-reference file to translate Laboratory Information System (LIS) result codes to Centricity EMR observation terms.

Specific Questions:

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

Varying definitions of "authorized person" between states often impose policy-based limitations on how providers can use and exchange laboratory results. This variation makes it more difficult to provide workflows that allow results to be exchanged with other providers directly or through a Health Information Exchange. Clarification of the CLIA definition of "authorized person" or "individual responsible for using the test results," given current EMR and HIE technology, should be considered.

The American Clinical Laboratory Association has proposed changes (see <http://wwwn.cdc.gov/cliac/pdf/Addenda/cliac0906/AddendumQ.pdf>) to the CLIA regulations that would enable better use of Healthcare Information Technology to support the exchange and sharing of clinical results.

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.

Verification of laboratory interfaces is a critical element of meeting this requirement in 493.1291 (a). Such verification is made more difficult by the variations in standards and terminology used. Even though most laboratories exchange information using the HL7 Version 2 standard with our EMR products, there are numerous variations in the version and specific options used in that standard in the exchange. GE Healthcare recommends adoption of HITSP selected standards for these purposes to ensure that patient specific data is accurately and reliably send from the lab to the Electronic Medical Record system. This approach would enable organizations like NIST to provide testing resources that would support the verification of these interfaces.

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

The "final report destination" is usually the ordering provider, but this interpretation is changing as the HIT landscape evolves. For example, instead of sending the report directly to the ordering provider, it could be sent to the HIE for access by the ordering provider and by consulting providers treating the patient. Current CLIA regulation have not yet adapted to these changes, resulting in difficulties in developing policies that enable HIE’s to facilitate the ordering and sharing of laboratory result

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, a universal compendium containing a standardized list of tests and results, and the codes and units used to report them, will reduce costs. Even though no compendium can realistically cover all laboratory tests, statistical analyses have shown that approximately 95% of the most commonly ordered tests can be ordered using a list of about 200 different orders

Who is best suited to maintain a universal compendium?

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GE Health Systems

Consensus-based standards organizations are best suited to this task. These organizations enable input to be obtained by all stakeholders, not just laboratory or EHR vendors.

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

We recommend the standards already identified by the HIT Standards Committee and ANSI/HITSP and recognized by the Department of Health and Human Services in January of 2008. These are:

- HL7 2.5.1 for orders and results
- CDA for laboratory reports between EMR systems
- LOINC for the transmission of lab test order codes and results
- SNOMED CT for identification of specimens, anatomy, pathogens and diseases
- UCUM for the representation of units.

We recommend that the Committee evaluate adoption of HITSP specifications as a way to support good, informed technology decisions.

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

We limit the automatic data transfer to specific data transfer workstations on either end of the communication link, and encrypt communications between the lab and provider site using standard encryption protocols (e.g., VPN or using Transport Layer Security). Once received, information is secured in our database and access to it is protected by role based access controls

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

Workflow within an HIT system – Such workflows are more of an obstacle than are technological limitations.

-Lack of “readability” of the lab reports for non-clinical persons - To effectively provide lab information to patients without context or real-time physician discussion requires some level of translation of these reports into language that is understandable and useful to a lay person (again, addressing workflows and content).