

Questions from the HIT Policy Committee / Information Exchange Workgroup:

General Questions:

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

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

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

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

Federal and state laws restricting the release of lab test results may impede the electronic exchange of lab data. In very general terms, the regulations issued under the Clinical Laboratory Improvement Amendments (CLIA) limit the release of test results to the individual responsible for using the test and to "authorized persons," defined as an "individual authorized under State law to order tests or receive test results, or both."

The phrase "individual responsible for using the test" is not defined, but is generally understood to include the person who ordered the test.

State law varies with respect as to whom is authorized to order or receive test results. In some states, labs are permitted to release test results only the person ordering the test. This means, for example, that specialists to whom a patient has been referred may not be able to access test results directly from a laboratory.

This framework may also impede the ability of patients to obtain copies of test results directly from laboratories. Although the HIPAA Privacy Rule gives patients the right to see and copy their protected health information, there is a carve-out for information that is subject to CLIA. In general terms, laboratories may only release test results directly to patients if permitted or required to do so under state law. Some states expressly prohibit labs from releasing test results to patients without the permission of the provider who ordered the test. This restriction may complicate patients' ability to have lab test results uploaded directly to their PHRs.

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

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

- What best practices would you recommend in this area?

Patients should be permitted to obtain copies of their test results directly from a laboratory after a brief period of time which would allow a provider to interpret the results and discuss them with the patient.

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

Specific Questions:

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

-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.

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

-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?

-Who is best suited to maintain a universal compendium?

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

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

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