

## **Questions from the HIT Policy Committee / Information Exchange Workgroup:**

### **General Questions:**

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

While the process to achieve electronic exchange of laboratory data is complex, expensive and technically demanding, we believe there are no overwhelming technical impediments to this goal. We view the process as having many similarities to the widespread use of credit cards where virtually any qualified individual can present a card, obtain a service and receive a detailed list of expenditures at the end of the month. Further, depending on personal choice, an individual can receive information of card usage online through the internet in a confidential manner. As with financial transactions, one of the most important considerations for electronic laboratory exchange is security, but again, we maintain that it is more difficult to steal electronic medical records than written or paper records and further, the ability to monitor access to electronic records is much greater than for paper records or medical charts.

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

The business cases for the use of electronic laboratory data are well defined. The applications of these cases in the public health workplace are an extension of the more general issues in the private sector, meaning, the need to respond to service requests by customers. In the public sector, these customers most commonly are epidemiologists and infectious disease specialists to confirm or exclude disease in a specific individual. However the business cases for public health extend broadly to include the real time monitoring of the public's health at the population level. These multiple business cases are illustrated by the need to determine changes in the number of confirmed cases of 2009 H1N1 at the national level, monitor effectiveness of current formulations of the vaccine in a specific state, and detect antiviral resistance in a specific patient or individual.

There are business processes that are unique to public health. One of the best examples is the selective need to strip patient identifiers from the lab result. However this and others have been successfully addressed. A second example is the language in HIPAA guidelines covering the transmission of laboratory reports to the public health authorities.

The business impediments to electronic laboratory messaging are primarily related to financial considerations; investment resources within public health laboratories are very limited and it has been difficult to address the high cost of purchasing and maintaining systems and software applications. The purchasing of up to date LIMS has been partially addressed through funds provided by CDC's bioterrorism preparedness program. The second most important business impediment is the difficulty finding and retaining information technology specialists within the laboratory. In addition, legal constraints and the development of agreements between the multitudes of government entities pose significant barriers.

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

This is a particularly important question. As a result of the APHL's involvement in the improvement of our national capability since the detection of anthrax in the US mail, we have acquired special understanding of the operational impediments. These impediments can be separated into three different categories including vocabulary, messaging, and architecture. Our members have written monographs and articles on these topics and for purposes of this testimony we will provide high level summaries and are willing to provide more information if requested.

**Vocabulary:** We have documented a wide variation in the use of different terms to describe the key elements of a laboratory test including the test name, the analytes or targets being tested and the results being reported. While one approach to address these differences is the use of standardized codes, we have also documented specific problems with the common application of test order and result codes. While it is possible to select a high level LOINC code that appropriately encompasses all tests for influenza, we advocate that more specific test codes are needed to convey and discriminate the performance of, for example, a real time polymerase chain reaction (PCR) procedure that is capable of detecting Influenza virus A 2009 H1N1 from a non real time PCR assay that detects Influenza virus A H1N1 of the seasonal type. The issue of vocabulary is addressed in more detail below under the committees question related to the use of a compendium.

**Messaging:** Following the harmonization of laboratory vocabulary for test ordering and result reporting, it is necessary to achieve uniformity in the creation of the electronic message. Again, great misunderstanding exists on the topic because it has been generally believed that if laboratories would simply comply with guidelines established by HL-7, then the messages would all be the same. The decision as to which element within the HL-7 message to convey certain data can result in multiple incompatibilities. To address this problem, APHL and CDC identified the most experienced experts in the country and engaged them in the PHLIP effort to develop a unified interpretation and application of the HL-7 guidelines. For more information on how to access the PHLIP messaging guidelines created for Influenza, please email [patina.zarcone@aphl.org](mailto:patina.zarcone@aphl.org).

The most significant remaining impediment is the provision of a message validation service. Such services are provided by insurance companies to assist the medical providers with compliance with messaging guidelines for electronic medical billing. We expect to deploy (within States themselves) such a message validating service for public health laboratory messaging in the near future, however a similar service is needed for the laboratory community at large and we envision this would be a great benefit to the nation if it could be implemented by a federal agency such as CMS.

Architecture: Data exchange architecture refers to the hardware and software as well as security processes needed to accomplish the goal of data exchange. Again, the PHLIP community researched the various approaches, brought in experts and engaged in the process of national debate among the various partners. A number of challenges were encountered including that some of the most modern approaches had not yet been validated by federal security experts and since messaging with federal partners was essential, older but more proven approaches were taken. The second challenge was that new approaches were being developed on a regular basis, an example being cloud computing, and these new approaches held many attractive features. However, implementing these new approaches and vetting them through State IT systems proved problematic because State IT directors did not want to change their systems for a seemingly small new activity. This meant that public health laboratories had to implement a system that could be called the least common denominator, however the success of the project demonstrates that the most elegant technical solution is not needed to achieve the goal of national level electronic laboratory data exchange.

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

While impediments may exist, we believe it is important to identify opportunities that could be addressed by the regulatory process. One opportunity involves the first component of any test order or result and that is the message header where the patient identifying and physician ordering information is documented. A common challenge encountered by both the private and public sector is that 42 C.F.R. § 493.1291 does not require the patient contact information (address, phone number etc) to be collected at the time of a test order and further the physician or medical facility contact information is also not required. Therefore a test may be (and commonly is) ordered with the specimen and the test order request containing only the minimum information which is two unique identifiers for the patient or client such as a name or number or birth date. A forward looking regulation may also be directed toward including an electronic contact, such as the electronic or IP address of the physician or medical provider.

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

The APHL has modeled and implemented scalable systems for multistate laboratory data exchange using the principles and processes developed by the PHLIP effort. Expanding the pilot project involving the current six State public health laboratories (Iowa, Nebraska, Virginia, Florida, Colorado and Minnesota) to perhaps as many as 26 State public health laboratories would serve as a clear demonstration of the government's commitment to the national effort. Several obstacles were overcome by PHLIP including the need to harmonize vocabulary and messaging structures as well as the process for maintaining security throughout the system (described above). PHLIP drew upon the expertise of national specialists to address the problem of scalability of data exchange systems that require point to point security certificates for all parties.

While we believe the concept of regional health information exchanges (RHIO's) is correct, we are concerned by the business models that may require users to pay transactions fees. The requirement for a payment of fees by the public health sector would be prohibitive and further, the charge of a fee for transmission of data to the public sector, such as the test order for a

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specimen needing to be submitted to a public health laboratory for confirmation of a public health condition would negatively affect the process.

### **-What are priorities to facilitate easier/broader e-exchange of lab data, even if not low-hanging fruit/immediately actionable?**

We believe one of the actions that will have the greatest impact is the creation of a national master patient index (MPI). Even if a national system is not created, if State or local MPI's are available to cross verify the identity of an individual without the need to use identity matching algorithms then a great obstacle to data exchange will have been removed. While some identity matching algorithms have a less than 2% error rate, we believe that is unacceptably high when the nature of laboratory testing includes information related to such critical issues as HIV and cancer. We believe a system with an error rate under 0.1% is needed.

A second issue is that of the application of new approaches to data storage and transmission. One concept we have explored is the use of data tokens that represent the data and authorize an electronic connection to the original data generator, i.e. the laboratory. These tokens would obviate the need to certify that the data in the electronic medical record is accurate or has not been amended by a correction or detection of an error. The most important conclusion is that additional research is needed and new funding initiatives would greatly accelerate the long term goals of electronic data exchange.

### **- What best practices would you recommend in this area?**

We recommend that processes be established through either regulation or CMS guidelines for laboratories to utilize common test codes and vocabulary for tests of public health concern within the next year. The implementation of these practices would serve to familiarize all laboratories in the processes necessary for achieving electronic laboratory messaging and lay the groundwork for applying standards and common vocabulary to all tests within the next three years.

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

To address the problem of maintaining large numbers of digital identity authentication certificates with each laboratory considered to be a business partner, we have instituted a route-not-read hub and spoke architecture where each laboratory maintains one digital certificate with the hub. There are two route-not-read hubs currently in production within the United States – one in Florida and the other in Nebraska, and presently each hub can manage data from up to 30 different States (or entities). These hubs provide a secure queuing system that functions to send messages to a pre-designated recipient without opening the message.

## **Specific Questions:**

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

Most State public health laboratories take advantage of the HIPAA exclusion regulating patient identified data for public health purposes. However, in the case of reporting the test result to the

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person or agency submitting the test request, some states have significant concerns for the security of the data since the state cannot control access to the data once it is transmitted electronically to another entity.

**-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.

We have no concerns with the requirements defined in 42 CFR 493.1291.

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

This phrase has different meanings depending on the case; however, for purposes of services we provide to the private sector, the final report destination refers to the physician or test requestor. For the public sector, the term may refer to the primary physician or test requestor as well as the local or county epidemiologist and subsequently, the state epidemiologist and potentially CDC laboratories or a federal program.

**-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?**

Depending on the meaning of a universal compendium or dictionary, the concept has great potential for improving electronic data exchange. However, the problem is very complex and we don't believe a compendium by itself will be the sole solution. Several efforts have been undertaken at both the State and federal level to address this problem and they have universally failed for a variety of reasons. It could be argued that compendiums already exist, and the problem is not the lack of a term but the selection of the proper term. Such problems were observed and addressed as the PHLIP effort progressed.

**-Who is best suited to maintain a universal compendium?**

The answer to this question has a variety of answers depending on definition of the terms and general intent, however we believe the concept is right minded and PHLIP participants have explored a variety of approaches. We recommend an approach be taken to this problem that has not been generally discussed. In our opinion, the most appropriate approach to a common test vocabulary, data exchange codes, and messaging structure repository is for it to be incorporated into the test creation process. This means that manufacturers of a test should incorporate harmonized vocabulary and specified codes during the process of creating the package insert or label during the FDA review process. Such an approach would embed the harmonization process into the same effort that a laboratory goes through to create a new test in the laboratory menu. We recognize a transition period would be needed during which tests already in use would need to be retrofitted into the national system. This retrofitting is essentially what the PHLIP community was required to accomplish in order to facilitate common reporting of Influenza virus A H1N1 results.

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

For purposes of tests applied to human sources and specimens we recommend LOINC for the test name and SNOMED for the test result. Further, we recommend moving toward HL7 2.6 for messaging structure. We are aware of the value of moving towards HL7 3.0 however still recognize that even today very few commercial clinical LIMS are able to message in HL7 2.3 and most systems cannot communicate in 3.0.

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

The approaches for ensuring secure transmission of laboratory data are well established and follow national guidelines including data encryption and confidentiality agreements with those receiving the data.

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

This question raises many important associated issues. Most patients do not know that their laboratory tests are transmitted electronically to their insurance carriers in near real time. The systems for carrying this information are clear evidence that there are no significant impediments to the process. The insurance carrier has an understandable need to obtain verification that a test was performed in order to authorize payment. However, it begs the question as to who pays for the laboratory test and who owns the laboratory test result? The patient advocate would say that the patient has paid for the test and should obtain a result, but the system in place would imply the insurance company is in this role. Further, a physician might argue that the test results should first be transmitted by the medical provider; otherwise the news of a positive test for HIV or cancer might be misinterpreted or lead to an over-reaction. If recommendations provided above were adopted, the patient could receive a laboratory report by any of the means that physician's offices currently receive laboratory test results, i.e. surface mail, fax, email or internet mediated repository.