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Introduction.

My name is Steven Hinrichs and I am Director of the Nebraska Public Health Laboratory at the University of Nebraska Medical Center. Today I am representing the Association of Public Health Laboratories having served as past chair of the APHL Informatics committee. I am currently national co-lead of the Public Health Laboratory Interoperability Project (PHLIP). On behalf of APHL and public health laboratorians, I would like to thank the members of the Meaningful Use committee for the opportunity to provide testimony regarding efforts within the laboratory community to utilize meaningful use concepts.

APHL's mission is to promote the role of public health laboratories in shaping national and global health objectives, and to promote policies, programs and technologies, which assure continuous improvement in the quality of laboratory practice and health outcomes. APHL represents public health laboratories at the state and local level and the laboratory scientists who serve within those laboratories. Laboratory scientists function as first responders, protecting the public from diseases and environmental health hazards but also provide confirmatory capability for investigations related to conditions caused by infectious agents and dangerous chemicals. Avian influenza, anthrax, contaminated water, *E. coli* and Salmonella have all been the subject of our investigations. You will undoubtedly hear continued testimony about the importance of accurate information and intelligence. Public health laboratories play a critical role in the protection of citizens of all states through the performance of confirmatory laboratory tests for diseases of public health importance. In that role Public Health Laboratories are a critical resource for providing actionable information and creating knowledge from disconnected data elements.

Our organization has been actively involved in state and federal activities focused on electronic exchange of laboratory information and our membership has acquired special expertise in all aspects of this critical function. In collaboration with our colleagues at the Centers for Disease Control and Prevention, we have led a transformation in the ability of public health laboratories to participate in health information initiatives. There is now a general acceptance that PHL's must not only be experts in generating data, but must also be leaders in the processes and strategies for electronic exchange of information. APHL is also a founding and board member of the Joint Public Health Informatics Task Force (JPHIT), an organization of Public Health partners dedicated to advancing the national capability of public health in all aspects related to information exchange.

I will summarize two projects that illustrate the value and importance of concepts related to meaningful use and their impact on public health. This summary will emphasize how these projects are and how the laboratory community in general is engaged with stage 1 measures of meaningful use including Electronic Laboratory Reporting (ELR), Immunization registries and Syndromic surveillance systems.

PHLIP.
For the past four years we have been engaged with our partners in the implementation of national data exchange standards and electronic messaging systems. The project, referred to as the Public Health Laboratory Interoperability Project (PHLIP) has developed scalable systems and processes to achieve the electronic exchange of essential laboratory test orders and results for purposes of surveillance, surge capacity and continuity of operations. Therefore this one measure, ELR actually impacts many other measures incorporated into meaningful use guidelines.

While syndromic surveillance is one important use of ELR, the public laboratory community has emphasized another critical aspect of electronic messaging and that is transmission of test orders. In general, as the term Electronic Laboratory Reporting is applied in public health, it refers to the transmission of laboratory reports related to conditions of public health concern, also known as reportable diseases such as Salmonellosis or tuberculosis or lead poisoning. However, laboratories transmit data about the organism or chemical that causes the disease. Therefore, all laboratory tests require interpretation and that data must be presented in a uniform and understandable way. Therefore we emphasize the importance of common data elements, uniformity in testing methods and processes that ensure quality. That is why APHL supports the use of not only national, but international standards for laboratory test reporting. Just as diseases do not recognize artificial boundaries at state or city borders, diseases do also not stop at national borders.

A common challenge encountered by the laboratory 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.

The laboratory community has learned through disasters such as hurricane Katrina and epidemics such as Swine flu that reporting of results alone does not capture the full capability of information technology. The ability of the state laboratory in Iowa to come to the aid of Louisiana was made possible through establishing a web based system for receiving test orders and submitting results. The business cases for electronic laboratory data are well defined. The application of these use 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 extends 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.

We respectfully submit that the dialogue needs to progress beyond the limited concept of electronic laboratory reporting to that of laboratory information messaging, which refers to not only the transmission of laboratory test results but also the electronic transmission of test orders. For purposes of the public health business case, the ability to transmit, acknowledge and respond to test orders is crucial. The ability to monitor test orders could be one of the earliest indicators of a change in health conditions or as means to detect outbreaks of new disease.

PHLIP has dramatically altered the ability of public health laboratories to participate in electronic laboratory messaging. The first pilot project established the requirements, processes and resources needed to bring public health laboratories on par with private sector laboratories. Three components were developed, all requiring different skill sets and knowledge. These three components included creation of the electronic laboratory test message which was accomplished by IT experts knowledgeable in HL-7. Significant obstacles had to be overcome because it had been generally believed that if laboratories would simply comply with HL-7 implementation guidelines the messages would all be the same and all data elements could be discriminated. This was found not to be the case and several decision forks were uncovered in the HL-7 message design which resulted in multiple incompatibilities. To address this problem, APHL and CDC engaged experienced experts to develop a unified interpretation and application of the HL-7 guidelines.

PHLIP documented a wide variation in the use of different terms to describe the key elements of a lab 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 found that more specific test codes were needed to convey and discriminate the performance of a real time polymerase chain reaction procedure that is capable of detecting influenzavirus A 2009 H1N1 from a non real time PCR assay that detects Influenzavirus A H1N1 of the seasonal type.

This subsequently resulted in agreement by subject matter experts in the use of appropriate descriptive language to describe the laboratory methods and corresponding LOINC and SNOMED terms or the creation of new codes when concepts such as multiplex PCR were not previously established. This was primarily accomplished by teams of laboratory scientists with knowledge of IT principles. The third component was system architecture and messaging hardware, security design and software including message validation and data repositories. This latter function was accomplished by IT experts with little or no knowledge of laboratory processes.

The original goal of PHLIP was to develop messaging structure and harmonized vocabulary for all tests related to 50 reportable conditions. However, the acuity of the influenza H1N1 outbreak resulted in all efforts to be focused on messaging of influenza. Efforts continue with messaging guidelines in near final form for Salmonellosis and other diseases. Other conditions such as tuberculosis will require significant additional work. One outgrowth of the PHLIP effort is an initiative to work with the FDA during the new device or assay approval process to achieve uniformity in test order and result vocabulary and coding.

A workbook and toolkit as well as a descriptive manuscript were published following the demonstration project in which four state PHL's and the CDC participated. These efforts set the stage for a nation-wide effort to commit all public health laboratories to being fully capable of electronic laboratory messaging. As of today, 15 state PHL's have been validated by the CDC as capable of messaging influenza laboratory reports. The project is well on track to bring 26 states into full production this year. Unfortunately, not all 50 state PHL's will have this capability.

Our last general observation is related to the vast disparity in capability for electronic lab messaging across the country. This disparity is true not only for state and local health laboratories and departments but also for doctor's offices, clinics and hospitals. No doubt the HITECH and ARRA funds will greatly impact further development of capability for ELR and other meaningful use efforts. While state laboratories participating in PHLIP have or are implementing state of the art systems with multiple information technology experts and hardware and software analysts and programmers, others still do not have operational laboratory information management systems (LIMS), or are using systems that operate at only the HL7., 2.0 or 2.2 level. HL-7 version 2.5 is far in the future for these laboratories. Even more disappointing is that some labs, even those at the federal level must report results by mail or at best by facsimile.

A second project administered by APHL will begin to address this gap in functionality. The goal of this new HITECH funded project, called the Laboratory Technical Implementation Assistance for Public Health (LTIAPH) cooperative agreement through the Centers for Disease Control and Prevention is to provide state/territorial/large and local public health laboratories and other state/local health agencies with access to needed technical assistance to extend their capability to enable not only the sharing of laboratory test orders and results within the public health community, but to also allow them to participate fully through application of meaningful use measures to better inform clinical decision makers at the point-of-care. Building upon principles and approaches shown to be successful in the PHLIP program, the LTIAPH CA will begin to address national disparities in capability.

However, the gap in capability between public health and the private sector is expected to grow because of funding difficulties at the state level. The uncertain fiscal situation facing public health laboratories and public health agencies across the country has resulted in a lack of funding to purchase needed information technology infrastructure and the inability to hire and retain needed technical

expertise to implement and sustain electronic data standards. If there is no infrastructure, the lessons learned through PHLIP will not be leveraged. The LTIAPH cooperative agreement will be one important vehicle to provide technical implementation assistance and resources to help public health laboratories to communicate with state and local health departments. This will be done by configuring laboratory information management systems (LIMS) to support state-of-the-art data standards resulting in strengthened capacity around laboratory data transmission and interoperability across the healthcare continuum.
While the goals of this project will take the next step in assisting public health laboratories to connect with hospitals and clinics, the funding received was relatively small in relation to the goals and expectations put forth.

Summary.

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. The measures of meaningful use related to ELR, syndromic surveillance and vaccine registries do provide an appropriate base on which to build.

The PHLIP program has shown that rapid progress can be achieved and that the Public Health Laboratory sector can be relied upon in the future to support critical functions related to public health including early detection of disease outbreaks and confirmation of disease cause. The public health laboratory community encourages the meaningful use committee to move beyond the phase 1 measures.

The impediments to electronic laboratory messaging are related to financial considerations; investment resources within PHL's are very limited and it has been difficult to address the high cost of purchasing and maintaining systems and software applications.

-What is 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 seven state PHL's to perhaps as many as 26 state PHL's 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 structure 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 specimen needing to be submitted to a PHL for confirmation of a public health condition would negatively affect the process.

-What's a priority 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 able 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 CMA 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, APHL has created a

route not read hub and spoke architecture where each laboratory maintains one digital certificate with the hub.

Specific Questions:

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

This question may have more relevance to private sector data exchange as most state PHL's take advantage of the HIPAA exclusion regulating patient identified data for public health purposes.

-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. However, for the public sector, the term may refer to either the primary physician or test requestor as well as the local or county epidemiologist and subsequently, the state epidemiologist and potentially the CDC laboratories or the 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 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 lab data are well established and follow national guidelines.

-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 technical 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 lab test and who owns the lab 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 lab test results, i.e. surface mail, fax, email or internet mediated repository.