The Affordable Care Act, Meaningful Use, and Their Impact on Public Health Laboratories

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While much discussion of the Affordable Care Act (ACA) has focused on improved access to medical care through expanded insurance coverage, the effect on the laboratory community has yet to be determined. Laboratory testing plays a critical role in health care, with more than 70% of medical decisions based on laboratory results.[1] One important aspect of the ACA is its mandate for improvements in the way laboratory test results are exchanged and transmitted to electronic health records (EHRs), including a process for "meaningful use" of laboratory data throughout the medical care continuum.[2] (Meaningful use refers to getting laboratory data back to the point of care for use by clinicians to make better, more informed, and meaningful decisions for their patients.)

The benefits of laboratory test results extend beyond primary patients and their physicians. The impact of meaningful use reaches to public health authorities at the local level who are responsible for tracking outbreaks of new conditions such as antibiotic resistance or seasonal disorders such as influenza or West Nile virus infections.[3] This public health impact results from improved reporting of certain laboratory tests to health epidemiologists who can share the discovery of unusual trends with state and national experts. Therefore, while much of the discussion regarding the impact of the ACA on laboratory testing has focused on data usage and lower costs, public health laboratorians are working to prepare for a much different outcome. This effort is needed to prevent well-intentioned plans from producing the unintended degradation of public health laboratory (PHL) preparedness and services.

Testing services provided by PHLs have traditionally been covered by public funds, including city, county, state, and federal sources. This support has paralleled the priorities of political leadership and the recognized need to control outbreaks of disease and maintain the public health. To ensure that all potential cases were found, the cost of obtaining the appropriate screening test for such diseases as acquired immunodeficiency syndrome was covered by the local health authority. These assays are referred to as screening tests because they are performed even when the patient may have no symptoms, as may be the case for detecting lead poisoning in children or Chlamydia infection in

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women. One of the major changes brought about by the ACA is that tests for screening purposes will be covered by third-party insurance companies. Because a large number of previously uninsured individuals will acquire benefits that include screening tests for preventable and treatable diseases, a major impact on public health is expected. As a result, the public sector may be relieved from this expense. The problem is that many PHLs have used the funds received from public sources to perform tests for screening purposes as a way to cover their core operational costs. As with many commercial enterprises, PHLs provide some services that carry a larger proportion of the operating costs than others. Some services have little margin and are provided only to meet local needs. As the ACA takes hold, universal insurance is expected to pay for all types of testing, including tests that have traditionally been within the public health domain, such as testing for sexually transmitted diseases. Therefore, traditional testing services performed by PHLs may cease. The expectation is that there will be no reduction in test services because the work will be done by the private sector. The result is that PHLs will either cease to exist or be required to compete with the private sector, including those laboratories with national reach.

During the next five years, the greatest impact of the ACA on PHLs is expected to be on test services provided solely for epidemiologic purposes; that is, to detect the outbreak of an epidemic or to demonstrate the likelihood of contamination of food or water supplies, such as the confirmation and subtyping of salmonella, an organism that may contaminate vegetables or fruit. One strategy for survival calls for PHLs to provide these specialized services to multiple accountable care organizations within a region. Another strategy is for the PHL community to demonstrate to the public health authority that some patients are unlikely to obtain screening services for certain diseases with a social stigma, such as gonorrhea; therefore, public funds must be set aside for the PHL, or disease control would be eventually lost. In other words, under either scenario, PHLs must redirect their efforts. To accomplish this goal, the PHLs must be on par with the private sector in terms of electronic test ordering and reporting. In addition, PHLs must become expert in other key capabilities such as third-party billing. Fortunately, PHLs have been preparing for this change for the past six years through a variety of collaborations with each other and with federal and state programs.

One of the most successful programs that has laid the groundwork for this transformation has been the Public Health Laboratory Interoperability Project (PHLIP).[4]

Since 2006, the PHL community, in collaboration with the Centers for Disease Control and Prevention (CDC), has been working to improve the information technology infrastructure to increase the use of cutting-edge data standards and interoperability protocols by the public health system. These improvements have allowed PHLs to exchange health-care information in a secure, standard fashion that is on par with the private health-care industry. This project, conducted under the auspices of the Association of Public Health Laboratories (APHL), assisted the public health community with incorporating industry standards to exchange laboratory test results and remain relevant in an ever-changing political and technological environment.

The U.S. Department of Health and Human Services Office of the National Coordinator for Health Information Technology developed concepts and processes involved in implementing meaningful use for health-care electronic information exchange.[5] Provisions of the ACA identified more than $600 million for the private health-care industry to meet the national goals, but very little funding was allocated to public health programs directly. Public health will benefit, however, when the health information mandated by meaningful use is directed toward the public health authorities. The assumption is that public health will be capable of receiving and using encrypted, secure, standardized messages from "eligible providers" (under the Medicare EHR Incentive Program, eligible providers include doctors of medicine or osteopathy, doctors of dental surgery or dental medicine, doctors of podiatry, doctors of optometry, and chiropractors; under the Medicaid EHR Incentive Program, eligible providers include physicians [primarily doctors of medicine and osteopathy, nurse practitioners, certified nurse-midwives, dentists, or physician assistants furnishing services in a Federally Qualified Health Center or Rural Health Clinic]) who are being incentivized to provide these data. CDC has been the leading federal agency responsible for preparing the public health community to receive these data, and several initiatives have improved the public health communities' capabilities. Through a combination of local and federal funds, PHLs have upgraded their infrastructures and implemented the required nationally recognized data standards, such as Health Level 7 (HL-7), Logical Observation Identifiers Names and Codes (LOINC), and Systematized Nomenclature of Medicine (SNOMED) Clinical Terms. Without CDC's support, local and state PHLs would be hard-pressed to meet the goals and opportunities provided by meaningful use.

Through PHLIP, the APHL has provided assistance to more than 53 state and local PHLs in the U.S. The

first priority of this work was to provide for electronic reporting of influenza virus test results to CDC and improve national monitoring. As a result of the PHLIP effort, 2012 data were transmitted directly from the Laboratory Information Management System (LIMS) to the CDC Influenza Epidemiology Division for active surveillance of influenza. With the advent of automated reporting and the elimination of manual reports, data are transmitted to CDC within minutes of a case being finalized, rather than weeks or months.[6] The opportunity now exists to expand to other diseases, such as measles, mumps, and pertussis, which could provide real-time information to CDC and state agencies on the success or failure of vaccine programs.

The success of PHLIP and the methodologies it created to help the nation's PHLs could also be used by public health agencies to assist with the receipt and processing of electronic laboratory reports (ELRs) from private institutions under the meaningful-use mandates. Along with vaccine registries and syndromic surveillance, processing ELR is one of the three public health-mandated activities for eligible providers within the meaningful-use criteria. Because each state may have a specific requirement for reporting certain conditions and diseases to the local public health authority, PHLs could provide valuable assistance to state public health agencies.

With assistance from CDC, APHL is moving forward to help public health agencies improve their capabilities to receive ELRs. The Electronic Laboratory Reporting Technical Assistance (ELRTA) program began in 2012. Through ELRTA, a public health agency can request technical assistance to achieve the opportunity provided by meaningful use. To date, 52 requests have been processed across the country, with assistance directed toward a broad array of needs, including system integration for end-to-end ELR messaging, data routing between disease surveillance systems, ELR message transformation to include LOINC and SNOMED coding, and messaging compliance to upgrade HL-7 2.3 messages into 2.5 formats. This work is already helping some public health authorities receive and use meaningful-use data from eligible providers and is expected to play an even larger role in helping meaningful use reach its full potential.

The ability to adapt to electronic data exchange will be a defining feature of successful PHLs in the future. At the same time that PHLs are facing funding challenges, they must adapt to a changing environment and develop capabilities in data collection, validation, and processing. If successful, the transformation of PHLs will result in improved monitoring of disease and make timely response to unexpected developments and new outbreaks of disease possible.

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