

# Supporting Public Health Laboratory Systems Research

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In the earliest days of public health laboratories (PHLs) in the United States, many PHLs were actively engaged in research activities, most of which were either basic or applied in nature. Some state PHLs were active in the development of vaccines, while others were active in the development of diagnostic assays and procedures. Over time, much of this type of research migrated to academic institutions and the private sector. Now there is a renewed research role for PHLs in the area of systems and services research. While basic research is hypothesis-driven, systems and services research examines the organizations, financing, and delivery of public health services in communities, and assesses the impact of these services on public health.<sup>1</sup>

During the past two decades, there have been a number of sentinel events and the release of several important documents and publications that reflect the ongoing evolution in the roles of PHL systems. In 1994, the Core Public Health Functions Steering Committee released the 10 Essential Public Health Services (hereafter, Essential Services), which were established to provide a guiding framework for the responsibilities of public health systems. One of the Essential Services is “research for new insights and innovative solutions to health problems.”<sup>2</sup> In 1998, McDade and Hughes published a seminal paper that described the need for a national laboratory system.<sup>3</sup> The Centers for Disease Control and Prevention (CDC) followed up in 2000 with its initiative to support a national PHL system.<sup>4</sup> This initiative evolved over time into the concept that the national laboratory system in support of public health in the United States actually comprises many state PHL systems, all working in concert with their respective partners.

In 2002, a publication entitled “The Core Functions of State Public Health Laboratories” was published.<sup>5</sup> As with the Essential Services, this publication, which was adapted from an Association of Public Health Laboratories (APHL) consensus document, also included public health-related research as a core PHL function. This report represented a new concept when compared with the historical view of the role of laboratories in public health practice.<sup>6</sup> Previ-

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ously, PHLs were seen simply as the providers of analytical services, while now they are being called upon to assume a broader role. Soon thereafter, CDC and APHL collaborated to develop a performance standards program for state and local PHL systems. This program formally became the Laboratory System Improvement Program (L-SIP) in 2008 and included research activity assessment as one of its measurements.<sup>7</sup> Most recently, a Healthy People 2020 goal was added that specifically called for measuring the performance of PHL systems at the state, tribal, and local level to support the Essential Services.<sup>8</sup> Measuring the performance of PHL systems in their progression toward meeting Healthy People 2020 targets includes a metric on research activities.

In recognizing the changing role of PHL systems with regard to research, APHL formed a Research Advisory Council (RAC) that convened in 2008 to identify the most critical research questions to address in support of improved system performance. The RAC recommended defining public health research using six research questions. They encompass the following areas of inquiry:

- What is the impact of the PHL system on the public's health?
- What quality systems assure PHL quality?
- What does it mean that there is a PHL workforce shortage, and what solutions are available?
- What do PHLs need (functionally) from the next generation of Laboratory Information Management Systems (LIMSs)?
- What does the ideal PHL system look like?
- What are the benefits of new technology?

Having established that PHL systems have a legitimate and valuable role in conducting research—particularly public health systems and services research—and focusing on the six identified thematic areas for research with defined research questions, APHL next addressed research support. Support for research may involve infrastructure, personnel, and funding. Even with state PHL systems that have close partnerships with academic research institutions, there is still a need for targeted funding. Most research activities in the health field are supported by governmental grants, foundations, or professional societies. Often, academic institutions will give researchers “seed” grants. The concept behind a seed grant is to award modest funds on a competitive basis to spur interest and possibly demonstrate outcomes that will ultimately lead to external support for research.

## THE INNOVATIONS PROJECT

APHL first established its Innovations in Quality Public Health Laboratory Practice Project (hereafter, Innovations Project) in 2010. Thus far, the program has been offered in three consecutive years (2010, 2011, and 2012), and 20 projects have received funding. The Innovations Project was designed to stimulate research activities in the areas of PHL systems, service, and practice. State and local PHLs were encouraged to create or further develop partnerships with other public health agencies, academic institutions, or laboratories in submitting their research proposals. The call for proposals asked the submitters to identify which of the six research questions was being addressed by their project proposal.

A selection process was established using objective reviewers who were asked to rate the proposals based on:

- Demonstrated understanding of the applicable research question,
- Generalizability of the proposal to other PHL systems,
- Specific proposal goals and objectives,
- Evaluation steps incorporated into the proposal,
- Evidence of collaboration with system partners and stakeholders, and
- Evidence of in-kind effort.

The proposals that were accepted received up to \$20,000 to support their projects. The funding support could not be used for PHL staff salaries. The submitters were encouraged to report their findings at the APHL Annual Conference and to publish their results in the peer-reviewed literature. Following are some improvements made through Innovations Project-funded proposals.

### Southern Nevada PHL PEWSS system

The Southern Nevada PHL received an Innovations Project grant that enabled it to evaluate and then expand its health district Pediatric Early Warning Sentinel Surveillance (PEWSS) system. The PHL recruited five pediatric medical practices in Southern Nevada to serve as sentinel sites for the PEWSS program. Sentinel staff collected specimens from ill children who met the influenza-like illness case definition, and submitted specimens for molecular testing for influenza and six non-influenza viruses. Laboratory results were analyzed and reported to the medical and general communities in weekly bulletins, which are used to establish viral respiratory seasonal baselines, and also in influenza vaccination campaigns. The surveillance program

was evaluated using the CDC Updated Guidelines for Evaluating Public Health Surveillance Systems.<sup>9</sup>

The program was well accepted by stakeholders who found it to be a useful public health surveillance system that is simple, flexible, accessible, and stable. Through the Innovations Project grant, the Southern Nevada Health District was able to fund the program in 2011 and 2012, and planned to expand the program to include additional respiratory agents in 2013.

#### **Arizona State PHL**

An Innovations Project grant awarded to the Arizona State PHL helped the laboratory create a crosswalk of the regulations, standards, and guidance documents affecting state environmental laboratories to aid in the process of meeting various accreditation and certification programs. The crosswalk provided a quick quality assurance guide for developing programs and integrating programs cohesively and uniformly. The crosswalk was made available for all PHL staff to use through the APHL Member Resource Center. The ability to quickly determine how standards and requirements relate to each other has allowed for a more efficient and effective quality management system.

#### **Texas Department of State Health Services Laboratory**

The Texas Department of State Health Services Laboratory received an Innovations Project grant to determine how best to deal with staffing shortages and the potential impact on laboratory services. The laboratory initially set up a three-day Lean Six Sigma training course, which provided participants with a foundation in the Lean philosophy for workplace organization.<sup>10</sup> The goal of providing the Lean Six Sigma training was to give participants the ability to identify, diagnose, and improve specific processes within the laboratory. The Texas Department of State Health Services Laboratory plans to continue moving forward with the implementation of Lean Six Sigma to execute more detailed, in-depth quality improvement projects.

#### **Wisconsin State Laboratory of Hygiene**

An Innovations Project grant allowed the Wisconsin State Laboratory of Hygiene (WSLH) to produce a guide intended to assist PHLs in conducting a LIMS needs analysis and requirements-gathering process. WSLH evaluated the efficacy of its needs analysis and reengineering efforts, and then organized the best practices identified into a package for other PHLs to use in completing their LIMS replacement/acquisition efforts. Information was obtained through a systematic

review of relevant documentation and interviewing stakeholders.

The project yielded an accurate and specific list of system requirements; a concise, yet comprehensive, documentation of all the major pre-analytical, analytical, post-analytical, and business processes used by WSLH; a core group of engaged project participants who helped build the project teams for LIMS implementations; the basis for several high-level and significant process changes that will have long-lasting positive effects on laboratory operations; and the establishment of clear communication channels for all stakeholders in the effort, including users, senior/executive leadership, and external vendor partners. Templates created or adapted for use by other PHLs included posters, presentations, tracking spreadsheets, training materials, workflow diagrams, and business process recommendations. The WSLH guide, which will be available through APHL, may also serve to assist laboratories with LIMS implementation after its selection and purchase.

#### **City of Milwaukee Health Department PHL**

The City of Milwaukee Health Department PHL (MHDL) received an Innovations Grant to focus on research activities as a key element of an ideal public health system. To facilitate collaborative research, researchers from multiple organizations convened to share areas of research interest and activity, which resulted in the creation of a research inventory. The inventory will continue to grow and be made available in a searchable online format. Community research leaders were better able to understand what networks were already in place and how they could complement each other's research strengths through L-SIP. The grant also facilitated the creation of internships in the MHDL project.

As a result of this project, the MHDL has gained insight into activities that could result in improved efficiencies. The MHDL determined that ongoing communication with stakeholders was particularly valuable in keeping it apprised of ongoing developments and receiving additional input. Overall, it was felt that this grant-funded work could serve as a model for other local PHLs that wanted to enhance their research output and aspire to go through the L-SIP process. The MHDL project is detailed in an article by Gradus et al. that appears in this supplement.<sup>11</sup>

#### **Arkansas Department of Health**

An award given to the PHL at the Arkansas Department of Health in 2010 enabled it to explore and

evaluate new biomonitoring technology, specifically liquid chromatography-tandem mass spectrometry, to detect synthetic cannabinoids (K2 Spice) exposure. K2 Spice is a mixture of herbs and spices that is typically sprayed with a synthetic compound that is chemically similar to the psychoactive ingredient in marijuana.<sup>12</sup> The information generated from this project has been used to educate and inform the community about the dangers of this illicit drug. In addition, numerous publications in the peer-reviewed scientific literature have resulted from this Innovations Project-funded work.<sup>13-15</sup>

## PUBLIC HEALTH IMPLICATIONS

Based on the three years of supporting projects conducted by PHLs in conjunction with their system partners, there is a clear indication that systems and services research is extremely valuable for continuously improving PHL systems in support of the Essential Services. Furthermore, all of the awardees stated that they would not have been able to conduct this systems and services research without the funding support offered through the Innovations Project grants. The six areas of focus outlined by APHL in 2008 continue to be important areas for inquiry and innovation. This type of research is essential to determine what works in public health and how to best structure, fund, and support the public health system and its various components.

Laboratories have been an important part of public health since their inception in the late 1800s. In 1993, Dowdle made the strong case for PHLs continuing to play an important role in the future of public health. He also noted that, "One feature that is common to all top public health laboratories is research."<sup>16</sup> There is no denying that the role of PHLs is evolving and the ways that PHLs are now being encouraged to operate within systems represent a change. PHLs are being encouraged to reach out to their partners and collaborators in the clinical, environmental, and agricultural sectors. They are also being called upon to strengthen their relationships with the end users of laboratory data and information, namely the public health program specialists and epidemiologists. Much of what laboratories continue to contribute supports disease prevention, surveillance, health protection, and health promotion. For PHLs to continue to offer such valuable support, they will have to engage in collaboration with their system partners in ongoing investigations and evaluations followed by the implementation of their findings. As these systems and services research projects expand and are disseminated,

they will contribute to an expanding body of literature that identifies the best practices for PHL systems. It is imperative that we identify a sustainable means for supporting and funding such important systems and services research going forward.

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## REFERENCES

1. Van Wave TW, Scutchfield FD, Honore PA. Recent advances in public health systems research in the United States. *Annu Rev Public Health* 2010;31:283-95.
2. Baker EL, Melton RJ, Strange PV, Fields ML, Koplan JP, Guerra FA, et al. Health reform and the health of the public. Forging community health partnerships. *JAMA* 1994;272:1276-82.
3. McDade JE, Hughes JM. The US needs a national laboratory system. *US Med* 1998;34:9.
4. Skeels MR. Toward a national laboratory system for public health. *Emerg Infect Dis* 2001;7(3 Suppl):531-2.
5. Witt-Kushner J, Astles JR, Ridderhof JC, Martin RA, Wilcke B Jr, Downes FP, et al. Core functions and capabilities of state public health laboratories: a report of the Association of Public Health Laboratories. *MMWR Recomm Rep* 2002;51(RR-14):1-8.
6. Valdiserri RO. Temples of the future: an historical overview of the laboratory's role in public health practice. *Annu Rev Public Health* 1993;14:635-48.
7. Association of Public Health Laboratories. Laboratory System Improvement Program: promoting system improvement. Silver Spring (MD): APHL; 2008. Also available from: URL: <http://www.aphl.org/aphlprograms/lss/performance/Pages/default.aspx> [cited 2013 Apr 12].
8. Department of Health and Human Services (US). Healthy People 2020: improving the health of Americans [cited 2013 Apr 12]. Available from: URL: <http://www.healthypeople.gov/2020/default.aspx>
9. Updated guidelines for evaluating public health surveillance systems: recommendations from the Guidelines Working Group. *MMWR Morb Mortal Wkly Rep* 2001;50(RR13):1-35.
10. Robinson AG, Schroeder DM. The role of front-line ideas in Lean performance improvement. *Qual Manag J* 2009;16:27-40.
11. Gradus MS, Bhattacharyya S, Murphy A, Becker JN, Baker BK. Milwaukee laboratory system improvement program (L-SIP). *Public Health Rep* 2013;5(Suppl 2):xx-xx.
12. Vardakou I, Pistos C, Spillopoulou C. Spice drugs as a new trend: mode of action, identification and legislation. *Toxicol Lett* 2010;197:157-62.
13. Seely KA, Prather PL, James LP, Moran JH. Marijuana-based drugs: innovative therapeutics or designer drugs of abuse? *Mol Interv* 2011;11:36-51.
14. Lapoint J, James LP, Moran CL, Nelson LS, Hoffman RS, Moran JH. Severe toxicity following synthetic cannabinoid ingestion. *Clin Toxicol (Phila)* 2011;49:760-4.
15. Brents LK, Gallus-Zawada A, Radominska-Pandya A, Vasiljevic T, Prisinzano TE, Fantegrossi WE, et al. Monohydrated metabolites of the K2 synthetic cannabinoid JWH-073 retain intermediate to high cannabinoid 1 receptor (CB1R) affinity and exhibit neutral antagonist to partial agonist activity. *Biochem Pharmacol* 2012;83:952-61.
16. Dowdle WR. The future of the public health laboratory. *Annu Rev Public Health* 1993;14:649-64.