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Linking Laboratories One by One to Strengthen America's Emergency Response System

Janis Thompson worked as a medical technician in a hospital laboratory for twenty-five years, followed by seven years as an infection control practitioner. In all that time, she said, she and her hospital colleagues "knew very little about what the state public health laboratory did." Aside from regulatory inspections, "I thought that all they did was (test) a few clinical specimens," she recalled.

Unfortunately that perception has been all too common among laboratory workers who are professionally removed from the world of public health. Today, as a training coordinator and program advisor for the Arkansas Department of Health laboratory, Thompson is part of a nationwide effort to reverse those prevailing misperceptions and build statewide laboratory communities that will collectively comprise what has come to be known as the National Laboratory System (NLS). (See additional information below on NLS.)

As with many recent public health laboratory initiatives, the push for the NLS was accelerated by fears of biological terrorism: almost simultaneously, laboratory leaders envisioned the Laboratory Response Network (see additional information below on LRN). Quite simply, the first sign of a covert release of smallpox, plague or other high-consequence agent is likely to be sick people. And the bulk of infectious disease testing performed in the US is not done in public health laboratories, but in clinical laboratories that are either affiliated with hospitals or see patients (or patient specimens) forwarded by private physicians.

While every state requires physicians and laboratories to report certain infectious diseases to public health authorities, historically the overall level of disease reporting has been low—perhaps as low as ten percent, according to Toby Merlin, the associate director for laboratory medicine in the CDC's Division of Laboratory Systems (DLS). Better connectivity among laboratories is expected to improve both disease reporting and the referral of disease isolates to public health laboratories for detailed analyses, including molecular comparisons of organisms infecting different patients to discern whether there is a common source of infection.

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Innovative Measures to Increase Connectivity
Laboratory program advisors like Thompson recognize the benefits of enhanced laboratory integration as well as the barriers. “Some of the labs have been very receptive (to overtures from the state laboratory),” she said. “Others are more prone to take a wait-and-see approach. Is this going to be regulatory or is it actually going to be beneficial to our laboratory?” To enhance connectivity, Thompson is planning distance-training workshops in laboratory techniques, dissemination of real-time disease surveillance data via a Web site and newsletter, and periodic teleconferences with hospital laboratory staff to discuss common concerns.

In Massachusetts, John Fontana is working on a project intended to strengthen ties between the state public health laboratory and hospital laboratories while simultaneously addressing a long-festering public health problem. Fontana, who directs molecular surveillance activities for the Massachusetts State Laboratory Institute (MSLI), is interested in “giving information back to hospitals” to help them better identify and control a community-associated strain of Staphylococcus aureus that is resistant to methicillin treatment. The problem of methicillin resistant Staphylococcus aureus (MRSA) is something “we’ve been staring in the face for years,” said Fontana. “It’s just not going to go away. It’s going to get worse.”

Fontana plans to collect MRSA isolates and associated clinical data from hospital laboratories—starting with the University of Massachusetts Memorial Medical Center—and subject them to advanced testing that is beyond the scope of routine hospital testing. The goal is to build a database of MRSA pulsed field gel electrophoresis (PFGE) patterns (essentially DNA fingerprints of the organisms) and drug susceptibility profiles that will help individual hospitals distinguish community-associated MRSA from healthcare-associated MRSA and to detect trends in disease prevalence and drug resistance. “We’ll do the PFGE and the analysis, but we’ll give (the hospital laboratories) the image database and training so they can monitor MRSA by ward or patient or employee. They can know what’s in their hospital and keep track of it.”

Fontana hopes the hospital laboratories will come to recognize the MSLI as a resource and will ultimately improve MRSA case reporting.

Although Fontana and Thompson have dedicated grant money to pursue their laboratory integration projects, virtually all state public health laboratories are pursuing similar kinds of activities, ranging from shared public-private specimen courier systems to formal agreements to share laboratory space during emergencies that create a surge in demand for laboratory tests.

Joyce Schwartz, the chief laboratory officer for Quest Diagnostics—one of the nation’s largest commercial laboratories—well understands the assets that public and private sector laboratories can offer one another. “We touch the vast majority of practicing physicians in the country between all the commercial labs,” she said. “It’s the benefit of our access that will hopefully lead the public health agencies to work more closely with us.”

On the flip side, Schwartz would like public health laboratories

to “off-load more mundane tests” (such as complete blood counts) to commercial labs and to share epidemiological data and validated assays for tests for emerging illnesses like SARS.

But Schwartz’s viewpoint may still be the minority opinion among private sector, clinical laboratory workers. David Sundwall, president of the American Clinical Laboratory Association (ACLA), said, “We’ve made the case, at least for ACLA members, that we don’t look at our work as competing with public health in any way.” Yet he said, “There is a history of collaboration with (public health laboratories and) individual (private) labs, but they are exceptions, not the rules.”

Centralization May Be Key

At the national level APHL, CDC, the ACLA and other partners are working on a number of projects to support state laboratory integration efforts. Perhaps the most popular of these is an effort to create a common, mechanized form that can be used in all state and local jurisdictions to detail the detection of a reportable illness, thereby replacing the multiple forms now in use. The CDC’s Merlin, who is heading the effort, said a standard form will “lead to better reporting and make it easier on the labs that do the reporting: a classic win-win situation.”

A second CDC project is the creation of the National Laboratory Database, which will eventually list all of the clinical laboratories in the country certified under the Clinical Laboratory Improvement Amendments of 1988. It would allow users to search for subsets of laboratories by location, type of testing performed, or other characteristics.

Just this summer the CDC will release findings from a national, formative evaluation of laboratory integration efforts. Based on surveys and personal interviews with public and private laboratory staff, the agency found that having a full-time person to coordinate activities with laboratories outside the state health agency made a huge difference in the level of integration achieved. Eunice Rosner, a CDC health scientist who monitored the evaluation process, noted that a variety of outreach activities—including electronic communication systems, dissemination of new microbiology information, and sending unknown specimens to clinical labs for identification—“all worked pretty well.” But, she said, “just having a person working with (the clinical laboratories) seems to be the main indicator of success according to preliminary results; if something comes up, clinical labs have a known person to contact.”

Forging More Than Just Clinical Connections

Increasingly the scope of laboratory integration efforts is expanding to new realms. Public health scientists realize that animal illnesses or contaminated soil or reservoirs are just as likely to signify biological or chemical terrorism—or other potential public health crises—as human illness.

Tony Sambol, assistant director and program advisor for the Nebraska public health laboratory, recalled an incident that occurred this summer involving a dead rabbit in Lincoln. The state veterinary science laboratory suspected that the rabbit was infected with Francisella tularensis: a naturally occurring animal pathogen that is transmissible to people and is on the CDC’s Category A (highest priority) list of possible bioterror agents. The veterinary science laboratory contacted a public

health veterinarian, who in turn alerted the state epidemiologist. The state public health laboratory confirmed the original diagnosis and reported back to relevant health authorities, which eventually determined that no one had been exposed to the rabbit. “This working together is why we do these (laboratory integration) projects,” Sambol said.

Sambol is overseeing a project to extend the use of a device, called STATPack®, to enable secure, real-time video transmissions of laboratory images. Alpha testing has been completed and five hospitals are working with the state public health laboratory as Beta test sites. “Now,” said Sambol, “we want to reach out beyond.” The plan is to implement the STATPack® system in four new venues: the veterinary diagnostic laboratory at the University of Nebraska-Lincoln, the hospital laboratory at Offutt Air Force Base, the food testing laboratory at the Nebraska Department of Agriculture and the state water testing laboratory.

If one of these facilities has “a colony (of organisms) that they believe might be *Bacillus anthracis,* they could send a video picture with all the pertinent facts of the case to the state public health lab,” said Sambol, thus speeding confirmatory diagnosis and emergency response activities. Moreover, he noted, “in the middle of the winter when the interstates are icy and closed, now we have another method to provide consultation.”

Connection with diverse types of laboratories “is just another aspect of preparedness,” said Sambol. “You don’t know if (an infectious or toxic agent) is going to be in the water, food, or livestock.”

Minnesota’s Louise Liao, who manages the state public health laboratory’s environmental testing program, is focused on water. The public health laboratory certifies many of the state’s private and municipal water testing laboratories, but “because (certification) is fee-based and because it’s regulatory, it does not have a flavor of collaboration,” explained Liao.

The public health laboratory would like to work more closely with these environmental testing laboratories, which have their own professional networks for staff development and quality assurance but have expressed interest in workshops to address common deficiencies in analytical techniques. “It’s a lot easier to do an inspection when the lab is already doing everything right than to punish them when they’ve never been trained,” said Liao.

The carrot for collaboration is training in E. coli testing. Environmental testing laboratories routinely test for the presence or absence of E. coli in drinking water—where even minute amounts of the fecal coliform are not allowed—but are eager to learn to quantify the amount of E. coli in swimming beach water—where anything under 200 to 235 colony-forming units per 100 milliliters water is considered safe. Liao explained that “just in the past two to three years, there’s been tremendous interest in swimming beach water nationwide. In a couple years, the US Environmental Protection Agency will require that swimming beaches be monitored for E. coli . . . and environmental testing labs are eager to provide high-quality analyses.”

In addition to training on the test methods, the public health laboratory will train on the quality assurance systems and, said

Liao, “that training will carry over to all of the environmental testing that the lab does on behalf of the residents of the state.”

As with all laboratory integration projects, a hoped-for by-product is greater referral of abnormal test results to the state public health laboratory so that emerging public health threats are identified quickly.
The ultimate goal, Liao said, is “a collaborative relationship where we all benefit from each other’s strengths.”

Additional Information on the National Laboratory System:

The National Laboratory System: A Work in Progress
Ask laboratory leaders, and they will tell you that there is no National Laboratory System (NLS) per se, despite the oft-repeated moniker. Instead, what exists is an ongoing effort, partially funded and otherwise supported by the CDC’s Division of Laboratory Systems (DLS), to create well-coordinated networks of laboratories in every US state—in essence a national laboratory system. Although the impetus for the project was the need to link private medical laboratories and state public health laboratories to speed the detection and reporting of possible bioterror agents, its scope has expanded significantly. Just this year the DLS—through APHL—awarded roughly $50,000 to each of ten states to carry out specific activities to increase the level of cooperation between the state public health laboratory and a defined subset of laboratories, ranging from hospital labs in Arkansas to water testing labs in Minnesota. While this dedicated support (and past support to NLS pilot projects in Michigan, Minnesota, Nebraska and Washington in 2000) has been a stimulus for innovation, all state public health laboratories—with or without DLS funding—are working toward the same overarching goals.

Additional Information on the Laboratory Response Network:

The Laboratory Response Network: Ready for the Worst
APHL and CDC established the Laboratory Response Network (LRN) in 1999 to improve the nation’s ability to respond to terrorist acts and other public health emergencies. Unlike the nascent National Laboratory System, the LRN has a well-defined operational plan and structure. The network is overseen by the CDC’s Bioterrorism Preparedness and Response Program and has three categories of members. A handful of national laboratories operated by the US military, CDC, and other federal agencies have the ability to identify specific strains of the most virulent and highly infectious agents. About 100 reference laboratories, including all state public health laboratories, can definitively confirm the presence of a threat agent, thereby initiating a chain of response. And thousands of clinical laboratories—those that have direct contact with patients—are responsible for identifying suspicious specimens and referring them to a LRN reference laboratory for a reliable diagnosis. Perhaps the network’s greatest asset is quality control: all reference and national members must meet stringent requirements for equipment, personnel and use the same validated protocols, giving test results a high degree of accuracy and comparability. Moreover, new tests are continually being brought on-line in anticipation of threats such as SARS and viral hemorrhagic fevers. Since its inception, the LRN has

received over $160 million in federal funding.

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