

NORTH CAROLINA'S PUBLIC HEALTH LABORATORY: SUPPORTING A BROAD RANGE OF TESTING NEEDS

by Emily Mumford, writer

North Carolina's public health laboratory currently occupies a five-story, 200,000 square foot building in one of downtown Raleigh's state government complexes: but not for long. By the early summer of 2009, the laboratory will break ground for its new facility, located to the west of Raleigh "in a pastoral setting," said the laboratory director, Leslie Wolf, PhD.

"The new lab will be on top of a hill, shielded from the road by a band of mature trees. The site is pretty, almost rural and it helps us meet some of our security needs—because of the hill and the protection from the road, we will not need to build a perimeter fence," said Wolf. Staff will be able to enjoy the views from the hilltop since the lab's modern design incorporates windows and natural light. "We have no windows right now on the laboratory floors," said Wolf, "and we are really looking forward to the light."

The laboratory will be newly co-located with the Office of the Chief Medical Examiner, although in fact separated into individual wings that will share meeting space and other common areas. A big challenge in the design process, said Wolf, was envisioning the lab's probable growth and creating a flexible space to accommodate testing needs for the next 30 years. In the end, she said, the new facility will only grow modestly larger, to 213,000 square feet, since the design lends itself "to more efficient, usable space."

As this project emerges, North Carolina's 216 public health laboratory employees continue to work, coming up with creative ways to transcend technical and space limitations in the old building. Challenges do arise though, and not all of them have been easy to solve. The issue of the day: "The state has sold our parking lot," said Wolf, "and it impacts employee parking and our modular BSL-3 unit."

In an unusual twist, losing the parking lot is endangering the continuity of the lab's PFGE testing. "We have been using our modular BSL-3 unit—currently parked right outside of our building in that lot—to do our PFGE testing," explained Wolf. "We couldn't produce high quality gels inside the lab building because of the power quality. The modular unit has a dedicated power line, so there are far fewer fluctuations. It's been a reasonable solution while we construct a new space." Wolf paused. "But since the unit was not built to perform PFGE testing, our staff relies on the main facility for supplies like high quality water, that kind of thing."

Each day the laboratorian hauls supplies back and forth between the lab and the modular unit. "We actually tease her a good bit about her little red wagon,"

laughed Wolf. Continuing, she said, "Now we're having to look at rental space or other interim measures, and time is running short."

Fortunately, there are fewer immediate concerns in other testing areas. North Carolina's public health laboratory receives one million samples per year and turns out five million to six million test results. Operating with a \$22 million budget, the lab draws \$3.6 million from federal grants; \$2.3 million from appropriations; and \$16.2 million from fees, supplies sold to other labs and Medicaid receipts. "This formula has changed dramatically in the last several years," noted Wolf. "Formerly we operated off of 75% appropriations."

The state offers a broad range of testing—cancer cytology, microbiology, virology, serology, newborn screening, clinical chemistry and environmental sciences, which includes organic and inorganic testing, environmental microbiology, radiochemistry and an office to certify other labs conducting safe drinking water tests. There is also a robust training component, called the laboratory improvement program and a lab preparedness component, which encompasses bioterrorism/emerging pathogens and chemical terrorism.

HIV testing is the lab's highest volume program, with more than 200,000 tests last year. Also in place is a novel testing program for acute HIV infection, the result of collaboration among the Health Department's HIV-STD program, the public health laboratory and UNC-Chapel Hill. The program identifies newly infected patients who are highly infectious but have not yet developed antibodies. Samples that yielded negative results through traditional HIV testing are pooled and tested for HIV RNA. During the pilot year of the program, 20 newly-infected HIV patients were identified and moved into care quickly, "ideally allowing them to stay healthy, longer," said Wolf. "This program has been so successful that after three years of support through corporate sponsorship, the state decided to pay for it. It has helped identify college outbreaks, protect pregnant women and their babies and halt transmission during this critical time."

Another unique program for the public health laboratory is benefiting women who seek gynecological care through Health Department clinics—

typically a higher-risk population. The lab receives the cervical cell samples from pap smears and uses a ThinPrep® Imaging System that identifies 22 areas of interest on the slide, allowing cytology staff to screen more quickly. If atypical squamous cells of undetermined origin (ASCUS) are identified in a patient more than 20 years old, the lab automatically reflexes to an HPV test. (ASCUS results indicate potential for infection, but could also be harmless, making these results difficult for doctors to interpret.) “For the HPV test, we use the Digene Hybrid Capture 2® assay—the only FDA-approved test at the time we started the program—and look specifically for high-risk genotypes,” said Wolf. “This additional information has really helped our healthcare providers determine what course of treatment to pursue for each patient.”

The laboratory also receives 130,000–135,000 samples for newborn screening per year and tests for more than 30 disorders. “We have been trying to meet the March of Dimes’ recommendations,” said Wolf. “We’re close. We actually were one of the first states to begin using tandem mass spectrometry, so we were able to add a lot of new tests in a small period of time. However, we are one of the last states to add a cystic fibrosis test to our panel. We received legislative approval this summer, and we are very excited to roll out that test in January 2009.”

North Carolina also has a hearty training component through its lab improvement section. Staff work with local, hospital, physicians’ office and environmental labs and develop targeted training programs. Recently there has been a focus on web-based training. “Our first web-based program was about collecting quality specimens for newborn screening,” said Wolf. “It covered when to take the blood sample, how to collect it properly, drying the card, filling out the information, what happens when these things aren’t done properly, why it’s important, how to submit the sample... It has been very successful for us.”

This kind of work resonates with Wolf and her ties to public health. “The lab has such a broad impact on people—and we touch many people every day. We ensure people have good drinking water and that their babies are healthy,” she remarked. “It doesn’t get much more personal than that.”

Wolf earned her bachelor’s degree in microbiology at the University of Kentucky. She then left her home state to earn a doctoral degree in immunology from the University of Colorado’s Health Sciences Center. There, at the Barbara Davis Center for Childhood Diabetes, Wolf worked on xenotransplantation, studying which immune cells were involved in the phases of rejection. “After five years of working with the mice and rats, I was ready for something a little different,” she said.

Wolf relocated to Raleigh, NC and began her post-doctoral work at North Carolina State University. She then accepted an APHL/CDC EID post-doctoral fellowship at North Carolina’s public health laboratory. The

fellowship focused largely on the tickborne infection ehrlichiosis. “I moved from the rats to mashing up ticks,” said Wolf, with a laugh. After this fellowship, Wolf accepted a new full-time position at the laboratory and spent several years developing assays and performing technology transfer. “PulseNet was a new program, and it kept me pretty busy,” she recalled. Later, as the assistant lab director, Wolf remained busy, learning in detail about the full scope of the laboratory’s work.

Now, as director, Wolf has responsibility for the entire laboratory and its direction. Two goals top her list: building the new facility and unifying their laboratory information management systems (LIMS). “We plan to launch our new LIMS—we’re working with the STARLIMS program—across the board by the end of the year. We have decided to use it for every single area of testing to achieve consistency.”

“Like many people in public health, mine was a long and winding path,” said Wolf. “But I’m so glad to be here... and I am proud of the lab, of the dedicated staff and the work we do every day.” ■

A new well-water program yields a large quantity of samples, nearly 26,000 annually. North Carolina now requires water quality testing for every new well. Local health departments collect and submit the samples to the state public health laboratory in Raleigh.

