In the Summer 2014 edition of Lab-Oratory, I summarized the North Carolina State Laboratory of Public Health’s (NCSLPH) platform to develop a strategic plan that will be used to provide a clear picture of defining where NCSLPH is headed in the next 3-5 years, what the lab will plan to achieve, the methods by which we plan to succeed, and the metrics by which we will measure our progress. The foundation for the strategic plan will be rooted in assessing the current North Carolina State Public Health Laboratory System using a process known as the Laboratory Systems Improvement Program (L-SIP) which targets improvements to the Public Health Laboratory System through the collaborative work of partners and stakeholders. L-SIP has been utilized in state public health laboratory systems in the United States to assess the system’s performance, plan for system improvements, implement improvement strategies, evaluate effects of the strategies and re-assess system performance.

On September 23, 2014, North Carolina became the 31st state public health laboratory system to complete an L-SIP assessment. Approximately 85 partners representing various parts of the North Carolina public health laboratory system, such as clinical microbiology laboratories, local health departments, newborn screening advisory committee members, state veterinary and agriculture laboratories, public water supply staff, law enforcement, information technology specialists, researchers, professional society members, program staff, and members of the North Carolina General Assembly, attended the event that was held at the McKimmon Conference and Training Center in Raleigh.
 Assessing essential public health laboratory services allowed stakeholders in the system to identify relative strengths and weaknesses. The discussion of key ideas and voting on the level of performance for each key idea shed light on the areas of high performance and those most in need of improvement. A Quality improvement plan has been developed from the NC L-SIP Assessment, and assigned priorities and anticipated time frames for completion. While the 10 Essential Public Health Services were individually evaluated, several predominant themes emerged during the assessment process. Quality improvement activities were grouped according to these themes that include the following:

1. Information Technology: Connectivity and Reporting
2. Financial Considerations: Sustainability and Growth
3. State Public Health Laboratory System: Organization, Oversight and Roles
4. Relationship Building: Coordination, Cooperation and Collaboration
5. Enforcement Activities: Routine Rule and Statute Review
6. Miscellaneous Activities

Through these quality improvement initiatives, opportunities for networking, coordination, cooperation and collaboration will be explored in order to better deliver the 10 essential public health services to the people of North Carolina.

I look forward to reporting in future editions of Lab-Oratory on the progress associated with our quality improvement initiatives and detailing of the NCSLPH Strategic Plan. As NCSLPH establishes its roadmap to ensure that our resources are working toward the same goals of the entire system’s stakeholders, we will continue to engage our partners and rely on their input. Together, through collaboration and partnership, we will establish a sustainable Public Health Laboratory System in North Carolina!

Submitted by:
Dr. Scott J. Zimmerman, Director
North Carolina State Laboratory of Public Health
N.C. Department of Health and Human Services

Influenza Surveillance and the Influenza A/H3N2 Vaccine Mismatch Dilemma

This year North Carolina had a more severe influenza season than in recent years. Many North Carolina residents became ill even though they were vaccinated against influenza. What’s the story?

How do we know what influenza strains are out there?

The WHO (World Health Organization) was established in 1947. Worldwide there are five WHO Collaborating Centers for Reference and Research on Influenza. CDC (Centers for Disease Control and Prevention) in Atlanta is one of the five and the representative for the United States. One of the objectives of the WHO is to determine human influenza type prevalence in order to support the production of effective vaccines to the world’s population. To determine the circulating human influenza virus types, a worldwide surveillance network contributes human influenza virus samples and isolates. Using these circulating influenza viruses contributed by the network, virologists working for the WHO and CDC analyze and predict what type of influenza viruses are likely to be prevalent during the next influenza season. The WHO influenza season for North America generally is considered to run from October 1 through the end of April the following year; however, influenza surveillance is year-round. As a collaborating laboratory in the WHO network for more than 40 years, the North Carolina State Laboratory of
Public Health (NCSLPH) submits viral samples to CDC each year in support of this effort. North Carolina surveillance sites voluntarily submit samples on patients presenting with flu-like symptoms. Located throughout our state, these sites include small and large hospitals, private and public health clinics, and some college infirmaries. The NCSLPH then tests these samples for influenza viruses using a molecular assay called PCR (Polymerase Chain Reaction). This assay looks for specific RNA found in human influenza A and B viruses. All positive influenza samples are then subtyped or genotyped using PCR to look for the specific RNA of the circulating types of influenza. All of the results from the NCSLPH are reported weekly to the WHO/CDC network. Most of the surveillance samples submitted to the NCSLPH are also cultured in traditional viral culture cell lines. Selective positive original samples and their companion culture isolates are submitted to the CDC for the WHO surveillance program. From surveillance site sample submissions, each year the CDC further characterizes about 2000 samples to compare how similar the current vaccine matches to the circulating viruses.

How does the CDC/WHO make the prediction of the vaccine for each year?

The influenza virus is a made up of a limited number of proteins called HA (hemagglutinin) and N (neuraminidase). Each influenza strain has a combination of these proteins and constantly reshuffles them changing the viral structure gradually or sometimes dramatically from the currently circulating ones. When gradual changes or mutations occur, the term is called “drift.” When more major mutations occur, the term is called “shift.” Based on past history and the current strains of influenza that are
seen from the surveillance program, scientists at CDC and WHO try to accurately predict what strains of influenza might be seen in the next season and consider how these influenza viruses might mutate either by making a shift or a drift. Since influenza vaccines are needed each year by everyone, a large volume of vaccine is required. The predicted influenza strains for the upcoming season must be determined early in the year, so that vaccine production can produce adequate amounts of a safe vaccine to serve the needs of a large population.

**Why did we have an influenza virus this season with a vaccine mismatch?**

Since vaccine determination must occur early to produce the volume of vaccine required and must undergo many steps in the process before the vaccine is approved, influenza strains have time to cleverly mutate before the vaccine is available for the next season. From beginning to end, the vaccine production process takes five to six months. The strain that the vaccine is based upon may not exactly match those emerging new mutations. This season, an Influenza A/H3N2 that was circulating in the 2013-2014 season was the strain that the United States vaccine was based upon. It did not perfectly match the vaccine and one that was not. Having two Influenza A/H3N2s circulating caused increased severity of disease in those who acquired the illness. Elderly people and those immunocompromised are usually at greatest risk for influenza. Unfortunately, even though some of the people in this population were vaccinated, deaths occurred in North Carolina. Similar incidences occurred throughout the United States.

**What about next season?**

This year the WHO met in Switzerland on February 23-25 to decide on the composition of the Influenza vaccine for 2015-16. The U.S. Vaccines and Related Biological Products Advisory Committee (VRBPAC), that is part of the Food and Drug Administration, considered the WHO recommendations and met to determine the vaccine composition for the U.S. On March 4, 2015, the WHO recommendation was endorsed by this FDA advisory group. The 2015-16 vaccines will change two of the three influenza strains that are in the current vaccines. The 2015-16 vaccines will include the newer Influenza A/H3N2 Switzerland-like virus, and the Influenza B component will now include Influenza B/Phuket-like virus. The new vaccines are usually available in the late summer or early fall, before influenza viruses cause widespread illness. There are now three types of Influenza vaccine technologies approved for use in the U.S. and several manufacturers of the various vaccine types. Some vaccines do not have an egg matrix, so that people who have a severe egg allergy may now be able to get a vaccination. Each of the vaccine types have recommendations and contraindications for those who may or may not receive that vaccine. Getting an Influenza vaccine early in the season is always a good move, unless it is contraindicated by your physician. Not only do you protect yourself, but you may also protect others who may be unable to get the vaccine.

For additional information on Influenza refer to the CDC website at [www.cdc.gov/flu](http://www.cdc.gov/flu).

Submitted by:
Susan Kilpatrick,
Specialist in Virology

References
QA, CQI, QC, QSE: What’s Up with Quality?

With the many current advances in science and technology, there is an ever-growing stream of new terms and concepts that are commonly referred to through the use of acronyms. Although these abbreviations make writing easier, they can be confusing if you are not familiar with them. Laboratory personnel are increasingly hearing the “Q” acronyms related to quality. Most of us are familiar with Quality Control (QC), but what about QA, QSE, QMS and CQI? There are many others, but these are ones routinely encountered in the laboratory setting.

Why are we hearing so many quality buzzwords? Let’s begin by exploring motivation, attitudes, and benefits accompanying the current emphasis on quality terms and processes. Healthcare managers and supervisors are well aware of the prevailing financial pressures and incentives to improve laboratory services. This climate has made it necessary to look at effective ways to assess and improve processes that will provide accurate, reliable, and relevant information to clients and patients, thereby increasing customer satisfaction. Building and maintaining a satisfied customer population are strong motivations for implementing quality processes. Improvements in quality are also beginning to be viewed as continuous and ongoing. In other words, the days of assuming we have modified and revised processes until they are perfect forever is over! There are always opportunities to improve and become more efficient.

Now let’s get down to what really counts – attitude! How do you feel about quality as it relates to your everyday duties? When you hear the “Q” terms, do you immediately zone out? Is the concept of quality vague and confusing? Do you feel like you’re already doing your best, and changes will only add to your workload and make life more difficult? If you answered yes to any of these, then you are probably among the majority of healthcare personnel struggling to understand “what’s up with quality!” However, without buy-in from employees on the front lines, it is difficult to implement quality improvements in an effective and lasting way. Change is difficult – it produces fear of the unknown, a possibility of failure, and the requirement to go outside of established comfort zones. On the positive side, change helps an organization to stay current, provides new opportunities, encourages creative thinking, and increases efficiency. And those are the very things that can improve our attitudes and our morale. Employee satisfaction also increases when workers know their suggestions and input are welcomed and valued and may be used to improve the way tasks are performed.

Aside from the benefits of change to our attitudes, quality improvement also provides for a reduction in errors and an increase in productivity and adaptability. Potential sources of errors are identified and fixed before patient care is impacted. Increased productivity and adaptability can ensure appropriate turnaround times and further enhance customer satisfaction. Let’s face it – without customers, there are no jobs, so meeting our customers’ needs benefits everyone!

The following are just a few of the most common “Q” terms we are hearing about in the laboratory. Keep in mind that these terms are not limited to the laboratory field, but can be applied to any business or activity. As you review the definitions, think of ways they apply to and affect your responsibilities.
• **Quality Management System (QMS):** A systematic, process-oriented approach to meeting a laboratory’s quality objectives. Elements of a QMS include policies, objectives, structures, rules, roles, responsibilities, practices and procedures.

• **Quality System Essentials (QSEs):** The fundamental, generic management infrastructure building blocks that support the laboratory’s technical work. Elements for the laboratory’s general structure include organization, facility and safety, personnel, equipment, and purchasing and inventory. Work elements include process control, documents and records, and information management. Measurement elements encompass occurrence management, assessments, customer service and process improvement. The QMS should establish policies, processes and procedures for each of these key elements.

• **Quality Assessment (QA):** A range of activities that enable laboratories to achieve and maintain high levels of accuracy and proficiency despite changes in test methods and volume. QA encompasses administrative requirements, standard operating procedures, corrective actions, and high-quality employee performance. QA may be summed up as a *failure prevention system*.

• **Quality Control (QC):** Activities to detect, reduce, and correct deficiencies in a laboratory’s internal analytical processes prior to the release of patient results. QC may be viewed as a *failure detection system*.

• **Continuous Quality Improvement (CQI):** A continuous and ongoing effort to achieve measurable improvements in the efficiency, effectiveness, performance, accountability, outcomes and other indicators of quality in services or processes.

The State Laboratory is committed to providing quality services to its customers and clients. We look at effective ways to assess what is done and how it is done so that measurable improvements can be made. Last fall, we hosted a meeting of laboratory system partners in an effort to identify areas where improvements are needed as well as areas of progress. This Laboratory System Improvement Plan (L-SIP) will be used in the coming months to facilitate improved performance of state and local Public Health Laboratory Systems. We are also beginning to develop skills in using the tools to perform lean studies on our internal processes to eliminate wasted time, effort and resources. As we embark on these projects, look for upcoming articles reporting what we have learned, obstacles encountered, and successful outcomes. As we see firsthand the benefits of quality, the “Q” words become more meaningful and more welcome in our vocabulary!


*Submitted by:*

Patty Atwood, BS MT (ASCP)
Laboratory Improvement Coordinator
EID Fellow Assists in Future Implementation of MALDI-TOF Technology

Hey there, y’all! My name is Vanessa Burrowes, and I am currently an APHL/CDC Emerging Infectious Diseases (EID) Laboratory fellow. Last August, I was assigned to the Bioterrorism and Emerging Pathogens (BTEP) Unit at the North Carolina State Laboratory of Public Health (NCSLPH). I am often seen running around between different departments for departmental shadowing gigs, various meetings, running phone call surveys/fighting the fax machine, and playing with the MALDI-TOF machine, but I suppose it’s time for a proper explanation. For a bit of a standard resume introduction about me, I graduated with my B.S. in Biology from “The” Ohio State University in Columbus, OH in 2012, and my MSPH in Environmental Health and Epidemiology from Emory University in May 2014. I was selected to be an EID fellow in June 2014, and now I am thrilled to be at NCSLPH, as I have had the opportunity to work at the local, federal, and non-governmental organization (NGO) level, but never at the state level!

Though I’ve only been at the State Lab a short period of time, my fellowship has kept me quite busy! Thus far, this fellowship has given me several opportunities to communicate my findings from various projects and ideas with public health leaders and stakeholders from around the Triangle area and beyond.

While I have several projects on my plate, my main project at NCSLPH involves a research collaboration with the biotechnology company, bioMérieux, in Durham, North Carolina. I am working with several wonderful people in the microbiology department to help build the microbial database for bioMérieux’s Vitek MS Matrix-Assisted Laser Desorption Ionization Time-of-Flight technology (Whew! It also goes by MALDI-TOF for short!) This relatively new technology is proving to be revolutionary in the world of microbiology over the past couple of years. While standard culture methods used to identify (ID) patient specimens from healthcare settings typically take anywhere from days to weeks, MALDI-TOF can ID bacteria, mycobacteria, and molds from intact cells in a shorter period of time. MALDI-TOF does so by analyzing and identifying unique protein fragmentation profile spectra that are produced after a culture sample applied to a target slide is irradiated with a laser, which ionizes the microorganism’s molecules. Analysis time typically needed for ID is cut back significantly to just under half an hour.

While several units here at the lab intend to conduct projects and validations on the MALDI-TOF, my project focuses on evaluating 1) the safety and 2) the accuracy of the Vitek® MS IVD (in vitro diagnostics) and RUO (research use only) databases for ID of BSL-3 select agents. To achieve the safety evaluation, I am first conducting several series of inactivation studies using bioMérieux’s protocols to successfully inactivate BSL-2 agents before moving on to working with BSL-3 agents. This inactivation study component is especially critical due to the fact that when a specimen arrives at the State Lab, laboratorians often do not know the ID of the bug they are working up. By evaluating the ability of these inactivation methods to effectively kill the microbe prior to application onto...
Hanging Out With the Fun Guy

I suppose my interest in mycology began in college during a soil microbiology class. I had to write a paper and I chose to write about *Hyphomycetes*. I was more familiar with *Basidiomycetes*, which includes tasty mushrooms, but class *Hyphomycetes* has predators! I specifically wrote about the nematophagous *Hyphomycetes* that use sticky knobs, nets, or rings that constrict to capture nematodes—small round worms that can be plant pathogens.

Several months ago the mycology section received a CAP survey that contained a *Beauveria* species. *Beauveria* species are entomogenous *Hyphomycetes* that infect insects such as lady bugs. And here I used to think all fungi were just placid, plant-like organisms!

Speaking of which, are fungi plants? Life is divided into five kingdoms: plants, animals, fungi, protozoa, and monera (bacteria). Fungi can’t make their own food like plants; instead, they excrete enzymes to digest food outside their bodies and then they absorb the digested material through their cell walls. Fungal cell walls are made of chitin and other polysaccharides, whereas plant cell walls are made of cellulose. Fungi also don’t differentiate cells into roots, stems, and leaves like plants—they are more primitive. Fungi exist as yeast, simple 3 to 5-micron diameter cells, or molds, 2 to 10-micron diameter filaments called hyphae. Dimorphic fungi can switch between forms.

Since I started working in the NCSLPH mycology section, we’ve had two dimorphic fungi. The first was a *Blastomyces* that I confirmed by converting the room temperature mold into its yeast form at 37°C. The second was a Histoplasma that had to be confirmed by the CDC. Sometimes living things don’t do what you want them to do.
Identifying molds relies heavily on morphology. I mainly look at spores and the structures from which they are produced. That means using a few different slide preparations to see these structures under a microscope. Hyphae are occasionally useful in identification. If there are wide, ribbon-like hyphae, it points to *Zygomycetes*, a class of rapidly growing fungi. Other fungi take much longer to grow. For this reason, our turnaround time is up to two months. I get very excited when I find conidia (asexual spores). Many are distinctive enough to give you the genus, such as *Bipolaris spp.*

Color can also help. If I have a red color diffusing into the media on which a *Penicillium spp.* is living, I need to be careful. It could be the dimorphic *Penicillium marneffei* that can cause systemic infections in immunocompromised patients or it might be *Penicillium purpurogenum* that infects strawberry plants. The antibiotic Penicillin comes from *Penicillium* molds so they can be helpful too. Molds aren’t always white and fluffy either. Some are very pretty and colorful, such as this purple *Fusarium oxysporum*. In fact, molds can appear in a wide variety of colors and textures.

To identify yeast, I use API strips with carbohydrate cupules. By evaluating the reactions on these strips, I generate a code based on the carbohydrates in which the yeast grows and a computer application uses this code to help me make an identification. I have to look at the yeast morphology on corn meal agar as well to make sure the morphology matches the API result. Chromagar is a selective and differential media I use mainly for identifying *Candida spp.* *Candida albicans* colonies, for example, are mint green on Chromagar.

These organisms help us make great things like antibiotics, bread, cheese and beer. They decompose matter such as dead trees that would cause a huge space issue if they never decayed. They can cause us discomfort from athlete’s foot, or even death from prolonged exposure to mycotoxins (*Stachybotrys chartarum*). I think you can see why fungi are important. The fungi kingdom has turned out to be more exciting than I first expected. Hope you’ve enjoyed a glimpse of what it’s like hanging out with the Fun Guy!

Submitted by:  
Melanie Mohr  
NCSLPH Microbiology Unit

Photo credit: Melanie Mohr
What’s Wrong with this Picture?
This is a packaging and shipping job gone wrong!
Can you identify the problems with this submission?

See answers on page 11.

Submitted by:
Kristy Osterhout
NCSLPH Safety Officer
### May-August

#### 2015 WORKSHOP SCHEDULE

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<td>June 18, 2015</td>
<td>Evaluation of a Stat Male Smear</td>
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Disclaimer: These Workshops are not intended to replace formal education but to enhance skills and promote use of recommended standard techniques.

For more information, consult our website or contact Lab Improvement at 919-733-7186

http://slph.ncpublichealth.com

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**ANSWERS FOR WHAT’S WRONG WITH THIS PICTURE?**

1. In a fine for that facility.
2. The postal service can be notified that posted specimens were packaged inappropriately which could result in a fine for that facility.
3. Blood lead samples have been submitted in the incorrect outer shipping container.
4. Samples will be reported unsatisfactory because they leaked.
Kudos to Employee of the Quarter Recipients!

Delshawn McLean of the Virology/Serology Unit is the first quarter recipient of the NCSLPH Employee of the Quarter award! Delshawn will celebrate 15 years of service as a North Carolina state employee in June. He has been an employee at the State Lab for 10 of those years. He has a BS in Biology with a minor in Chemistry and a MS in Administration. Delshawn is proficient in technology and instrumentation, and he is always willing to help his co-workers. Thank you, Delshawn, for your contributions to our laboratory!

The second quarter recipient is La’Vonda Benbow, Supervisor of the Mycobacteriology Lab. La’Vonda is being recognized for her leadership qualities and myriad of significant contribution to NCSLPH. Her professionalism, positive spirit and leadership aptitude are vital factors to her success and enhance a culture of accomplishment to the State Public Health Lab. Congratulations, La’Vonda, for a job well-done!

New Additions!

The State Laboratory welcomes the following new employees:

Virology/Serology – Lori Hood, Mark Turner, Adrian Morrison, Taneka Sanders, Anita Smith
Bioterrorism – Jennifer Gelpi
Newborn Screening – Nour Sarsour