DELAWARE HEALTH AND SOCIAL SERVICES

Division of Public Health

Laboratory

DELAWARE LABORATOR

SUMMER

2008

STRATEGIC PLANNING

Jane Getchell, DrPH, Laboratory Director

The mission statement of the Delaware Public Health Laboratory (DPHL) is "To provide accurate and timely laboratory data, information and consultation to enhance the health of the people of Delaware." This mission statement was established in January of 2000 and after more than eight years, it was time to look at it again. At a senior staff strategic planning retreat held earlier this year, a logic model analysis was conducted of each laboratory section to identify activities, inputs and outputs, as well as short and long term outcomes. Accomplishments for the previous year and goals for the upcoming year were also identified.

Dr. Paul Silverman, Associate Deputy Director for DPH, led the discussions. There were four major outcomes:

1. A suggestion to revise the mission statement to read: To provide accurate and timely laboratory data, information and consultation in support of the public health mission through the following core public health laboratory functions:
   - Disease prevention, control and surveillance
   - Integrated data management
   - Reference and specialized testing
   - Environmental health and protection
   - Food safety assurance
   - Laboratory improvement and regulation
   - Policy development
   - Emergency response
   - Public health related research
   - Training and education
   - Partnerships and communication

   These core functions were developed by the Association of Public Health Laboratories (APHL) in 2000.

2. Strategies identified for the future were to:
   - Prepare the DPH laboratory's infrastructure for the future - increase and stabilize funding, seek grant opportunities and fellowships, examine fee for service options, assure adequacy of the laboratory facility;
   - Assure adequacy of information technology – web-based reporting for newborn screening, Laboratory Information Management System improvements and access for non-state facilities, Public Health Information Network compliance and interoperability with the Centers for Disease Control & Prevention (CDC) and other state labs;
   - Assure adequacy of workforce – internships, broadening the career ladder, employee recognition programs, partner with the University of Delaware and other educational institutions and training;
   - Improve operations management – contracting, procurement, personnel management;
   - Enhance communication about the DPH laboratory - communicate the uniqueness of the laboratory, strengthen partnerships, address customer satisfaction; and
   - Expand services the DPH laboratory provides – implement DNA testing for cystic fibrosis and other genetic, metabolic and infectious diseases, hepatitis C testing, expand food testing.

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Strategic Planning, continued

3. Customer Satisfaction Survey

   Please visit the DPHL web site http://www.dhss.delaware.gov/dhss/dph/lab/labs.html and if you haven't filled out our customer satisfaction survey, we encourage you to do so. It will help us help you. The responses we have received thus far can be reviewed at http://www.dhss.delaware.gov/dhss/dph/lab/files/surveysummary.pdf.

4. Conduct strategic planning that involves laboratory partners - seek their input and mutual understanding.

   Healthy People 2010 recognized that every state should "provide or assure comprehensive laboratory services to support essential public health services." The state public health laboratory has a leadership role in developing and promoting the state public health laboratory system through active collaboration with stakeholders including epidemiologists, first responders, environmental laboratories, and clinical laboratories. The state public health laboratory system is a network consisting of all the participants in public health testing, including those who initiate testing and those who ultimately use the test results.

   DPHL has asked APHL to assist in planning and conducting a state public health laboratory system assessment for Delaware. Ultimately , we will be inviting stakeholders to meet face-to-face to go through an assessment tool with us. Data from the assessment will be used in building a comprehensive and vital strategic plan for the Delaware Public Health Laboratory System. We look forward to working with you on this important project.

FOODBORNE ILLNESS RESPONSE

Emily Outten, Health Program Coordinator, Health Systems Protection
Marion Fowler, MT (ASCP), Microbiologist II
Sue Shore, MT(ASCP), Foodborne Epidemiologist

Foodborne illness and foodborne outbreaks are a growing public health concern. Headlines about contamination of our food supplies attract the attention of everyone concerned about the safety of what they are consuming. It is extremely important for the Division of Public Health (DPH) to rapidly identify and investigate any possible foodborne illness outbreaks in order to quickly apply control measures to reduce the incidence of those illnesses. On June 20-21, 2008, DPH sent representatives from three different public health sections to the Epi-Ready Team training for foodborne illness response strategies offered by the National Environmental Health Association in cooperation with the Centers for Disease Control and Prevention and National Center for Infectious Diseases. The training was designed for the foodborne investigation "team" consisting of epidemiology, environmental and laboratory personnel. It stressed the value of the team working as a unit using the "three legged stool" model, which emphasizes the importance of all three areas working closely together for rapid and effective foodborne investigations.

The training consisted of several modules.

The first module discussed surveillance systems in detail, including active vs. passive surveillance. Surveillance is the process in which we track and identify possible clusters of illness or outbreaks from required disease reporting, complaint investigations, or laboratory data. Passive surveillance includes data collected from Delaware physicians, laboratories and other health care providers that are required by regulations to report patients with certain conditions to the Health Information & Epidemiology office. (See http://www.dhss.delaware.gov/dhss/dph/dpc/rptdisease.html.) Active surveillance includes investigations conducted by the Office of Food Protection (OFP) Environmental Health Field Services in response to complaints from the public.

In the next module we learned how to prepare for an investigation, how to verify a diagnosis, how to search for additional cases and then determine if the cases are associated. Emphasis was placed on the interviewing skills required to obtain accurate and valuable information to determine if an outbreak has occurred.

The investigation begins with determining the existence of an outbreak and then verifying the diagnosis. A case definition is constructed for determining if an individual's illness is associated with the specific investigation. It includes a clinical definition as

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Foodborne Illness Response, continued

well as restrictions by time, place and person and can be reviewed and revised as the investigation progresses. Using the definition, cases are identified and interviews conducted to collect data for analysis, performing what is known as **descriptive epidemiology**, the first leg of the stool.

An epidemic curve, or epi curve, is a graph of the number of cases by date or time of illness onset. It is the first piece of descriptive epidemiology.

The epi curve provides a visual display of how extensive the outbreak is and how long it lasted. A hypothesis is developed regarding the source of the infecting agent, how it was transmitted and what exposure (i.e. food) caused the illness. A hypothesis must be evaluated regularly to determine its feasibility. In order to do this, a study design is selected and statistical analyses are performed. Using information obtained from the study, the epidemiologist calculates measures of association between the exposure (food item) and the disease. Calculations comparing the number of illnesses of those exposed to a food item to those unexposed help determine the "culprit" in an outbreak. Computer programs help the epidemiologist with these statistical analyses.

Once the statistical data is generated, the epidemiologist needs to determine the validity of all the results. Is this information statistically significant or is it partially due to chance? There is also the potential for bias in any investigation, such as how well a person interviewed remembers exactly what he/she ate and when. At this point, the hypothesis needs to be re-evaluated and possibly changed or refined. Many times the hypothesis can never be proven or dismissed due to lack of complete information, such as specimen testing of ill cases, food testing, investigation population size, etc. Information resulting from the epidemiological investigation must be compared with laboratory and environmental studies to support or dismiss the hypothesis.

The primary goal of an outbreak investigation is to prevent additional cases of illness in the population. In practice, this step should be implemented as soon as possible. If a particular food item statistically shows association with illness, that food item must be removed from public consumption as soon as possible. This is particularly evident in multi-jurisdictional outbreaks when product recalls are issued due to associated illness (e.g., the recent spinach, pot pies, and tomato recall). Communication with the public is one of the most important steps in a foodborne outbreak investigation. A written report is completed as a record of the investigation and a document for possible legal actions.

The Office of Food Protection, the second leg of the stool, regularly conducts inspections of food establishments including restaurants, delis, camps, daycares, outdoor festivals, food processors, and farms. DPH environmental health specialists (EHS) are responsible for conducting inspections in addition to participating in outbreak investigations.

So why is it so important to assemble the team quickly, and perform rapid inspections, interviews, and food collections? Since food operations are not static, it is important to get into the food establishment as soon as possible. Food that is related to foodborne illness has often been discarded or consumed by the time the outbreak is detected. Personnel interviews can also provide some insight. The person in charge (PIC) of a food establishment should be able to demonstrate knowledge of food safety practices, and if the PIC does not have the knowledge, he or she can't pass it on to their staff. Interviews can also provide information about workers who may have been ill during the time period of interest and identify who has worked with implicated foods.

Following the interviews, the EHS should then perform a facility walk through to assess food preparation. The most common critical violation in the state of Delaware is the improper holding of hot and cold foods. During the facility walk through, the inspector can observe normal operations. They may check temperatures to make sure hot foods are being held at or above 140 degrees, and cold foods are 40 degrees or below. They may check hand washing stations for adequate soap and paper towels. They may also check sanitizer levels with test strips to make sure sanitizing solutions are at the proper concentrations. These are just a few of the violations the EHS would be looking for in an outbreak investigation.

After the inspections, the EHS would collect records and samples. Records could include absentee logs, temperature recordings, or simply just a menu of what was served during the period of interest. Sampling should be planned and coordinated with the laboratory in advance. This would allow inspectors to collect the proper type, size, and number of samples. Several companies manufacture food sampling kits, which allow for proper and sterile collection.

Following the interviews, observations, and collection of records/samples, the EHS then decides on control actions. These could include immediately closing the restaurant, restricting the sale of certain menu items or foods, recalls, or simply implementing risk control plans, additional staff training, or menu/supplier/recipe modifications.

Verification of diagnosis and food testing are an important part of foodborne outbreak investigation— the "third leg". Laboratory confirmation of foodborne illness is considered the gold standard when it comes to outbreaks. Without isolation of a pathogen from either a patient or implicated food, we are often unable to determine a definitive case.

Bags of cheese from the December 2006 E.coli outbreak come into the lab for testing.

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Foodborne Illness Response, continued from page

Laboratory testing of food is very complicated and requires different media, reagents, incubation temperatures and time, depending on the pathogen or pathogens implicated. The most likely suspect foods and the most likely suspect pathogen are determined based on the predominant symptoms of the sick, the time interval between eating the suspect food and the onset of symptoms, the duration of symptoms, and the results of prior testing. DPHL is contacted in advance with this information so that when food samples and/or clinical specimens arrive at the lab, the proper media is prepared and personnel are available to perform the testing.

Food samples are tested using standard cultural microbiological methods and may take two to five days depending on the pathogen. To decrease this time, real time polymerase chain reaction (qPCR) can be performed on enrichment samples of the food. The qPCR results are still confirmed by the cultural method but a preliminary positive result will help guide the team and aid physicians in treating their patients. Once the organism is grown, isolated and identified, serological testing and pulse field gel electrophoresis (PFGE), as applicable, are performed. The results will link together patients who have been exposed to the same pathogen.

As is evident, it is imperative that the Laboratory, Office of Food Protection, and Epidemiology work together in the event of an outbreak. The team approach is a positive approach for all sections involved, and we look forward to working together on the next big outbreak!

Please *respond to our laboratory services survey—www.dhss.delaware.gov/dhss/dph/lab/labs.html*

WEST NILE VIRUS SURVEILLANCE

Rebekah Parsons
Molecular Virology Lab Manager

West Nile Virus (WNV) is an arbovirus associated with nervous system disease that may cause inflammation of the brain with less severe cases presenting with only a fever[3]. West Nile Virus is transmitted to humans via biting arthropods, such as mosquitoes. WNV infection can cause West Nile fever, West Nile encephalitis, and/or West Nile meningitis. Symptoms resulting from WNV have been known to persist for up to five years following onset of infection.[2] Cases of WNV are likely underreported because persons with mild illness do not seek testing and treatment.

The Delaware Public Health Laboratory (DPHL) utilizes three different test methods dependent upon specimen type: a microsphere-based immunologic assay (MIA) for human specimens, an enzyme-linked immunoassay (ELISA) for chickens and horses, and a real-time polymerase chain reaction (PCR) for wild birds.

In 2007, DPHL tested 196 human specimens for the presence of IgM antibodies against West Nile Virus (WNV). IgM antibodies are the largest of the antibodies and are the first antibodies produced as a result of infection.[1] Testing is performed on a luminex platform produced by Bio-Rad. The luminex uses a microsphere-based immunologic assay (MIA) test that employs specific antibody labeled fluorescent microsphere beads to form an antigen-antibody complex. Currently, the MIA is used for WNV and St. Louis Encephalitis testing on human serum or cerebrospinal fluid (CSF). The MIA takes a minimum of two hours for one specimen and up to four and a half hours for an entire plate which consists of 40 specimens. The cost associated with running an entire plate for only a few specimens is prohibitive. Therefore, specimens are generally batched weekly. Only one human specimen was confirmed to be positive in 2007. Confirmation of suspected positive samples is performed by the Centers for Disease Control and Prevention.[3] In a CDC report listing WNV activity for 2007, the number of WNV cases in surrounding states was as follows: Maryland 10, New Jersey 1, and Pennsylvania 10. No fatalities were listed in Delaware or the surrounding states for 2007.

In addition to testing human specimens, DPHL performs yearly WNV and Eastern Equine Encephalitis (EEE) surveillance by testing sentinel chickens and wild birds. Ninety-two sentinel chickens are located throughout the state of Delaware. Four sentinel chickens are stationed at 23 designated sites. Two of the four chickens are alternately tested on a weekly basis. Previously, sentinel chickens were tested using a hemagglutination inhibition assay (HAI) for total antibodies. The HAI did not differentiate between IgG and IgM and therefore could not distinguish between past exposure and current infection. In contrast to IgM, IgG is the smallest antibody and persists following an infection or exposure to maintain lasting immune response. The 2008 WNV method for testing sentinel chickens consists of an enzyme-linked immunoassay (ELISA) to detect IgM antibodies. The ELISA method generates results of either positive or negative rather than giving a titer as the HAI. However, the specificity of the ELISA assay is greater than that of the HAI, eliminating potential false positives. In 2007, DPHL tested 1241 chicken specimens for WNV and 1059 chicken specimens for EEE. Twenty two chickens were reported as positive for WNV. There were no positive results for EEE.

The Department of Natural Resources and Environmental Control (DNREC) establishes the sentinel chicken program each year and is responsible for bleeding the chickens each week. Sentinel chicken surveillance began on June 16 for the 2008 season.

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West Nile Virus Surveillance Testing, continued

Testing results on sentinel chickens are reported to DNREC electronically as soon as they are available so that any necessary control action can be taken.

DPHL tests dead wild birds from April to November using real-time polymerase chain reaction (PCR). Viral nucleic acids are extracted from brain specimens and primers are used to amplify sequences specific to WNV. Tests on wild bird specimens totaled 440 for 2007 with 72 of those producing a positive result. Unlike sentinel chickens and wild birds, human specimens are tested year round.

References

1. Tizard, I., Immunology: An introduction, 3rd Ed. Orlando, FL: Saunders Publishing, 1992.
2. Voelker,R. Effects of West Nile Virus May Persist. *JAMA* 2008;299(18):2135-2136.
3. http://www.cdc.gov/ncidod/dvbid/westnile/

EMPLOYEE NEWS

We welcome **Kathleen Hukey (Kate**) as a microbiologist II in the molecular virology section where her work will focus on the food emergency response network — the rapid detection of foodborne pathogens in the event of a potential terrorist attack on the nation's food supply. Kate previously worked for the New York State Department of Health studying arthropod-borne diseases. She graduated from the State University at Albany with a B.S. in biology and plans to continue her education with a master's degree. In her free time, you can find her camping, hiking, canoeing and kayaking.

WELCOME KATE AND YAO!!

The environmental chemistry section welcomes **Yaohong Zhang (Yao)** as an analytical chemist III. Yaohong previously worked at the College of Marine Studies and Earth Science at the University of Delaware, employed as a research scientist and laboratory manager. At the DPHL, Yao is the principal inorganic chemist for the drinking water analytical program. Yao has a bachelor's degree in biology from Qingdao University in China and is close to completing her master's degree in marine studies at the University of Delaware. She enjoys cooking and gardening.

THANK YOU, FLU CREW & KUDOS TO THE MOLECULAR VIROLOGY SECTION!!

The molecular virology section is indebted to 'The Flu Crew' for their assistance during the mass influx of influenza specimens in February and March. In addition to their own daily workloads, these employees helped the molecular virology employees maintain a consistent workflow, ensure timely testing, and retain their sanity. Seeing support walk through the door and knowing that extra hands were forthcoming was a tremendous stress relief for them all. We can not praise them enough nor can we accurately convey the depth of our appreciation for their help. The true wealth of knowledge and expertise within DPHL is proven by these three people. Thank you, Flu Crew: (from left) **Pat Selg** (administration), **Mary Ann Brown** (microbiology), and **Pat Scott** (newborn screening)! Kudos to the entire molecular virology section for their hard work during flu season 2007-2008.

FEE INCREASE NECESSARY FOR NEWBORN SCREENING TESTING

Patricia M. Scott, Labortory Manager

In 2002 the Delaware Newborn Screening Program (NSP) acquired state of the art tandem mass spectrometry technology (abbreviated as MS/MS). This technology allowed the NSP to expand our screening panel to over 35 disorders including all 29 "core disorders" recommended by the American College of Medical Genetics expert panel in 2006. In 2006, the NSP expanded further by adding cystic fibrosis and biotinidase deficiency to the screening panel.

Beginning in January 2009, the Department of Health and Social Services, Division of Public Health will be increasing the fee for Newborn Metabolic Screening from the current rate of $78.00 per baby to $98.00 per baby. This fee will cover both the initial and repeat mandated blood spot screens, coordination of follow-up of babies with suspicious or abnormal results, and continued quality assurance and professional and public education activities across the state. This increase is necessary to support the operational costs of the Newborn Screening Program.

In addition to supporting ongoing program operations, the increase will also support acquisition of the next generation MS/MS equipment. A new MS/MS will enable the Public Health Lab to continue screening in an efficient and cost-effective manner. The new MS/MS will also make it possible for Delaware to further expand our screening panel and to develop second tier procedures now being used in many states.

Newborn screening is an established public health activity which, together with follow-up, rapid diagnosis and treatment, prevents cognitive disability, illness, and death in affected newborns. Newborn Screening has been demonstrated to be cost effective, saving expenditures for medical, educational and institutional needs which would be required if affected babies were not identified and treated promptly.

An effective newborn screening program can only operate effectively when there is collaboration among birth hospitals, primary pediatric care providers, families, pediatric specialists and the screening program. We are proud of how Delaware has been able to establish such collaboration and we look forward to it continuing.

If you have any questions please contact the Newborn Screening Program at 302-741-2990 or toll free at 1-800-262-3030.

DELAWARE'S DIVISION OF PUBLIC HEALTH LABORATORY

Delaware Public Health Laboratory
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Smyrna, DE 19977
302.223.1520
Fax: 302.653.2877

Built: 1990

Business Hours: 8 a.m. – 4:30 p.m.

Purpose: The Division of Public Health Laboratory currently offers consultation and laboratory services to state agencies, Delaware Health and Social Services and Division of Public Health programs including:

- HIV surveillance and prevention
- Immunization
- Lead
- Epidemiology
- Newborn Screening
- STD prevention
- TB Elimination
- Drinking water
- Preparedness

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If you have questions regarding these articles or would like to receive a hard copy of this newsletter, contact the Delaware Public Health Laboratory at 302.223.1520. To receive this newsletter by email, contact liz.moore@state.de.us.

"To Protect and Enhance the Health of the People of Delaware"

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