Nebraska Public Health Laboratory Newsletter

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NPHL Updates

By Peter C. Iwen, PhD, D(ABMM), Associate Director, NPHL

What an interesting time to be involved in laboratory medicine! New ideas and processes seem to be a common occurrence as described in some of the topics presented in this Spring newsletter. Tony Sambol provides an overview on the subject of chemical terrorism preparedness, a problem that only recently became something for consideration in the laboratory. He highlights the efforts of the NPHL in providing training to medical personnel throughout the state on this issue.

Robbin Williams, a health surveillance specialist at the NE DHHS, provides an update on the pandemic H1N1 influenza virus in our state. Over the years, we have continued to strengthen our working relationship with the DHHS which became even more important during this pandemic.

Gerald Capraro presents an article to update on the new activities as pertaining to GC/CT testing at the NPHL. He is the newest member of our team, came from Wake Forest University in Winston-Salem, NC to become a clinical microbiology fellow in our nationally accredited Committee on Postgraduate Educational Programs (CPEP) for postdoctoral training. Jerry began his 2 year training in July 2009 and has now become an integral part of the public health laboratory.

This issue extends our articles on meeting the laboratorian and CLIA updates from Dr. Sarewitz's audioconference. Joan Mares, UNMC Business & Compliance Manager provides the updates on the changes to the regulatory standards that affect all individuals working in the laboratory. This month we also highlight our latest laboratorian, Dan Griess, a medical technologist who became the CEO at Box Butte General Hospital. Highlighting individual laboratorians is one means for us to show how fortunate we are in Nebraska to have such talented and dedicated individuals in our medical practices.

The NPHL wants to emphasize the support we receive from our laboratory partners "in-the-trenches" and that without this support, we would not be able to provide the services necessary to help keep our citizens healthy. As always, we welcome your suggestions on topics for this newsletter and on how we can better serve you.

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All Events are Local - Hospital CT Preparedness

By Tony Sambol, MA, SM(NRM), Assistant Director, NPHL

"All Events are Local"- "Prepare for the Worst and Hope for the Best" – "The only thing worse than a bad plan is No plan at all"- "Practice, Practice, Practice!"

How many times have we heard these phrases in the past nine years? The world has certainly changed since the terrorist attacks that took place on the World Trade Center and Capitol Hill in 2001. In response, all state public health laboratories (SPHLs) have been working closely with the Centers for Disease Control and Prevention (CDC) Laboratory Response Network (LRN) since 2004 on Chemical Terrorism Preparedness efforts.

As such, all SPHLs have been charged with the responsibility of working with the stakeholders in their state to make sure that if a terrorist activity involving a chemical warfare agent took place, they would be ready to respond. The CDC LRN terms this as "CT Level-3 activities." More applicable to Nebraska, is the possibility of a naturally occurring accident or local terrorist activity involving exposure of people to a toxic industrial chemical or toxic industrial material. Since Nebraska is a large geographical area, the NPHL began a training process in 2005 for the major hospitals in each of the 20 public health districts. To date, most public health districts now have a hospital where personnel are trained in the collection, handling, shipping, and chain-of-custody paperwork that would be necessary if specimens were to be collected for chemical analysis.

The partnership between NPHL and the hospital facility begins in earnest with a cooperative agreement to have the hospital maintain an inventory to collect 100 patient specimens. This inventory is managed with the current supplies as to not expire. NPHL provides packaging and shipping materials to each site for immediate access to ship the 100 patient specimens directly to the CDC. Test order codes are recommended in the Hospital Information System to assist nursing and phlebotomy in what specimen containers to use and what specimens to collect. This step also generates labels which are necessary for the paperwork required, such as the chain-of-custody and the shipping manifest. Most importantly, NPHL provides annual training and in the case of an event, on-site assistance.

Since training is an ongoing issue, the NPHL is planning two broadcasts this year, in May, over the Telehealth Network. This training will highlight updates and changes in the program that the NPHL started in 2005 as well as being a good review for those hospitals that have already received the training. Hospital are invited to participate in this event. The hospital CEO, head Safety Officer, ED Director

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(CT Training, Continued from page 1)
and Laboratory Manager are encouraged to attend. The NPHL will be recording the broadcasts and making them available to all hospitals at a later date for those unable to attend. Announcements will be sent out as to the actual time and dates of the broadcast through a variety of means. We encourage hospitals to join us as "All *Events are Local"*

Pandemic H1N1 Update

By Robbin Williams, Health Surveillance Specialist, Nebraska DHHS

Flu seasons are unpredictable in a number of ways, including when they begin, how severe they are, how long they last and which viruses will spread and when. There were more uncertainties than usual for the 2009-10 flu season because of the emergence of the pandemic 2009 H1N1 influenza virus (previously called "novel H1N1" or "swine flu"). The Nebraska Department of Health and Human Services Division of Public Health (NDHHS-DPH) continues to work closely with our local health department (LHD) partners and the Nebraska Public Health Laboratory (NPHL) in addressing the various issues raised by the 2009 H1N1 flu virus. This article provides updated information and guidance regarding epidemiology, lab testing, antiviral use, and influenza vaccine.

Nebraska surveillance data indicate that influenza activity has dropped to a level below our tracking system's ability to detect, and may have totally disappeared from the state. This is based on 1) weekly surveillance of 81 Nebraska laboratories performing rapid influenza tests; 2) weekly surveillance of designated primary care physicians across the state who track influenza-like illness (ILI) in their practices; and 3) weekly surveillance of Nebraska hospital ILI admissions.

Since early September, 2009, all but one (which was an influenza A /H3 subtype in September 2009) influenza A viruses subtyped at NPHL have been the pandemic 2009 influenza A (H1N1) strains (n=525). Sporadic testing showed that these isolates were susceptible to oseltamivir (Tamiflu), zanamivir (Relenza), and peramivir but not to the adamantanes (Amantadine and Rimantadine). Rapid influenza testing has continued to decrease around the state, with fewer than 10 positive tests per week. Many of these are likely false-positives. Fewer than 10 specimens are being submitted weekly to the NPHL for confirmatory PCR testing. Providers should collect a rapid test on any person (hospitalized or outpatient) suspected of influenza, and should forward a naso-pharyngeal sample to the NPHL on any patient with a positive rapid flu test, or any patient strongly suspected of influenza, regardless of the result of the rapid flu test. The last positive specimen confirmed by PCR testing was collected on April 9, 2010, and was the pandemic H1N1 strain. The previous positive specimen prior to that was collected on March 29, 2010, and was also the same strain.

Although many people are now immune to this virus as a result of infection and/or vaccination, many people in the United States remain susceptible to the 2009 H1N1 virus. CDC flu experts have recently expressed concerns about a resurgence of influenza. The vaccination still remains the most effective means of preventing influenza. The vaccine should continue to be made available through provider offices, retail settings, and health departments. At this point, targeted outreach may be the most appropriate strategy, (e.g. to those at high risk of severe illness, to parents of young children who need to return for the second dose of vaccine, minority and hard-to-reach populations, college and university students, and people 65 years and older). Both the seasonal (trivalent) vaccine and the monovalent pandemic H1N1 vaccine can be provided to all persons who seek the vaccine provided they lack contraindications to the vaccine as stipulated in the package insert.

Nebraska

Sentinel Laboratory Surveillance 2009-2010

Season-to-Date (August 30,2009 - May 1, 2010) Totals

	All Influenza	Influenza A	Influenza B
Total Positive	4338	4261	77
Total Tests Performed	30825	30825	30825
% Positive	14.07%	13.82%	0.25%

Current Week's Influenza Data (week ending April 25-May 1, 2010)

	All Influenza	Influenza A	Influenza B
Total Positive	3	3	0
Total Tests Performed	117	117	117
% Positive	2.56%	2.56%	0.00%

RSV Surveillance	Current Week	Season-to-Date
Total Positive	9	1907
Total Tests Performed	106	8372
% Positive	8.49%	22.78%

New Recommendations for Routine Gonorrhea and Chlamydia Screening

By Gerald A. Capraro, PhD Clinical Microbiology Fellow

Neisseria gonorrhoeae (GC) and *Chlamydia trachomatis* (CT) are the two most common bacterial causes of sexually transmitted diseases (STD) in the United States. CDC estimates there are approximately 19 million new cases of STDs in a given year in the United States (of which, nearly 2 million of these are caused by GC/CT). The cost to treat these infections and their complications is estimated to be more than $8 billion per year (1). The gold standard assay for diagnosis of GC/CT has been culture from appropriate specimens. However, culture can be problematic if specimens are not handled properly and inoculated onto the appropriate media (GC) or into appropriate cell lines (CT) immediately following specimen collection. *Neisseria gonorrhoeae* is particularly susceptible to dehydration in the absence of appropriate transport media.

Laboratories that perform GC/CT screening *en masse* (e.g., public health and other laboratories that service STD clinics) often utilize an automated nucleic acid amplification test (NAAT). These tests have been shown to have excellent sensitivity and specificity, with a quick turnaround time of less than one day in many cases. The NAAT allows the laboratorian the ability to test for both GC and CT in the same specimen using species-specific probes, and eliminates the need for time-consuming and sometimes difficult culturing techniques. The most commonly used NAATs in clinical laboratories take advantage of polymerase chain reaction (PCR) technology (COBAS Roche Amplicor), strand-displacement (SDA) assays (BD ProbeTec), or transcription-mediated amplification (TMA) technology (Gen-Probe Aptima).

FDA-approved specimens for use in NAATs include endocervical swabs from women, urethral swabs from men, and urine from both men and women. These specimens provide excellent potential for detection of GC/CT using any of the methods listed above. Additionally, vaginal swab specimens are FDA approved for use in TMA tests. Schachter *et al*. recently reported that vaginal swabs were equal to or superior to endocervical swabs or urine for detection of GC/CT in women (2). Thus, vaginal swabs are now considered the preferred sample type for screening (2, 3, 4). Recently, extra-genital sites (rectal, oropharyngeal) have been identified as potential sources for the detection of GC/CT. These sites have been useful in the diagnosis of GC/CT infection in patients who engage in high risk sexual practices, such as men who have sex with men (MSM) or sexually active young heterosexuals who engage in unprotected anal or oral sex. In an excellent review by Renault *et al*., the sensitivity of NAATs using extra-genital specimens was at least as sensitive as culture for GC/CT (5). In patients with suspected rectal GC infection for whom rectal swabs were collected, TMA was considered the most sensitive test (100%), followed by SDA (78%), and PCR (54%) when compared to culture. When pharyngeal swabs were considered, the sensitivity of testing was again highest using TMA (95%), followed by SDA (75%), and PCR (66%). Where rectal CT infection was considered, the sensitivities for TMA, PCR and SDA were 100%, 92%, and 77%, respectively. In all cases, the specificity of extra-genital sites for NAATs was shown to approach 100%.

Rectal and pharyngeal infection among high risk populations remains a public health concern. The CDC currently recommends at least yearly screening for GC/CT for MSM since non-urethral infections are often asymptomatic and can be present in the absence of urethral infection (6). Annual screening for pharyngeal GC is also recommended for these individuals. In situations where a patient may have multiple sex partners or may participate in sex acts involving illicit drug use, CDC also recommends routine screening at 3 to 6 month intervals. Highlighting the importance of this recommendation, Kent *et al*. surveyed two STD clinics in San Francisco, CA with high MSM populations and found that 53% of CT and 64% of GC infections occurred at non-urethral sites (6). These infections would likely have gone undetected in the absence of routine extra-genital screening in this population.

Although the NAATs show an improved sensitivity for the detection of GC/CT infection, one drawback in using this methodology is the lack of positive cultures for additional testing. Of note is the inability to perform antimicrobial susceptibility testing on strains of *Neisseria gonorrhoeae*. Antibiotic resistance mechanisms are increasing among GC isolates, specifically to penicillin, tetracycline and ciprofloxacin. Due to this emerging resistance, the current CDC recommendation is that only cephalosporins be considered for the treatment of gonorrhea in the United States (7). For uncomplicated urogenital, anorectal, or pharyngeal GC, CDC recommends a single intramuscular dose of ceftriaxone (125 mg). In cases of suspected or diagnosed co-infection with CT, addition of a single dose of oral azithromycin (1 g) or a 7 day course of doxycycline (100 mg, twice daily) is recommended (7).

Culture has historically been considered the only forensic standard for the diagnosis of GC/CT infection in cases of suspected sexual abuse or assault. However, NAATs have now been seen as a reliable alternative for testing in these circumstances (8). A recent report from the Association of Public Health Laboratories in consultation with the CDC reported that NAATs were superior to culture for the detection of CT in cases of adult rape or sexual abuse in adults and children (9). It is however still recommended that confirmatory testing using a different NAAT be considered when positive NAAT results for GC occur in either adults or children. Black *et al*. showed that urine specimens tested by NAATs provided a clear advantage over culture in sensitivity and was less invasive than swabs (8). The authors also pointed out that urine specimens, as opposed to swabs, also reduced patient trauma and discomfort, which is especially important with children being evaluated for sexual abuse. To date, these recommendations have yet to be widely accepted by courts of law.

Currently extra-genital site specimens are not FDA approved for use in commercially available NAATs. Laboratories that consider adopting these specimens for testing must verify and validate that the assay performs with the highest levels of sensitivity, specificity, accuracy and precision, as compared to previously verified testing. These parameters are currently being evaluated by the NPHL for both throat and rectal specimens. Additional validation testing is being considered for vaginal and eye specimens in the future. Culture will still be available in the laboratory for unusual specimens or in cases where an organism is needed for additional testing.

(New Recommendations References on page 5)

CAP/CLIA Regulatory Updates

By Joan Mares MT(ASCP)SH, UNMC Business & Compliance Manager

Laboratories must review and perform method validation measures on all quantitative tests. These testing requirements include accuracy, precision, analytic sensitivity [lower level of detection], analytic specificity [note interferences], the reportable range and the reference range. If a test is Food and Drug Administration (FDA) cleared/ approved, these parameters must be verified with validation signed by the Medical Director of that discipline or of the laboratory. Analytical sensitivity, specificity and in some age groups, reference ranges can be obtained from the manufacturer. For testing that is not FDA approved, all 6 of the testing requirements must be established "in-house." This information is retained by the laboratory for the duration of that instrument plus 2 years, 10 years, or indefinitely depending on which agency's regulations apply. To establish a plan of action to satisfy the performance guidelines, the Clinical and Laboratory Standards Institute (CLSI) provides reference guidelines. For instance, CLSI document C28-A2 provides direction in determining reference ranges while EP5 gives guidance for evaluation of precision. When doing test validations, the matrix (e.g. specimen type of the testing fluid) also must be considered. Some tests must be run on several matrixes and all of them must be verified or established depending on FDA approval of the exact method used.

Once testing has been validated, College of American Pathologist (CAP) & Clinical Laboratory Improvement Amendment (CLIA) require proficiency testing (PT) be performed every six months. CLIA does not require that PT be done on waived testing although highly recommended. CLIA requires that PT be performed on all regulated analytes posted on its website.

Competency of personnel performing the test is required by both CLIA and CAP. In the first year a person works in the laboratory, competency assessment must be performed at 6 months and at 12 months, and annually thereafter. Specimen collection and critical result reporting were added to competency assessment criteria in 2007. This evaluation may be done by direct observational methods such as monitoring of testing records including, where applicable, critical results, review of test result worksheets, QC records, proficiency testing records, preventive maintenance records, evaluation of problem-solving skills and testing previously resulted assays. This monitoring is documented and kept in the appropriate personnel file or in another location designated for competency testing.

Personnel records are inspected thoroughly by both CLIA and CAP. CLIA personnel requirements can be found at *http://www.cms.gov/clia.* CAP requirements can be found in the CAP General checklist under "All Personnel".

Critical results are required to be notified to the individual or entity requesting the test results. When critical results are obtained, notification of these results must be made and documented on the test report. This is a Joint Commission, CLIA and CAP requirement. Individual hospitals generally develop a critical test list.

CAP requires that computer systems transporting patient results are checked for accuracy across interfaces. Laboratory reports must also be retained for 2 years [GEN.20377] unless longer periods are required (e.g., surgical pathology and cytopathology reports and blood bank reports). CAP [GEN.41310] also requires that on corrected reports, both the original result and the corrected result be present and identified. Computerized calculations [GEN.43450] must be checked every 2 years or after the system is changed in any way that could affect calculations.

Another area of CAP checklist questions involves Direct To Consumer (DTC) testing. If the laboratory offers any DTC testing, CAP has a number of phase II standards in the 2009 checklist. A laboratory that offers DTC testing must send the result to the patient's practitioner IF requested. The lab must give the patient contact information for a health care practitioner and the results must include an interpretation in lay terms. If the result is CRITICAL, the lab must contact the consumer with the results in a timely manner. These results must be retained for 10 years.

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CAP Checklist Updates, 2009 LAP Audioconference Series sponsored by The Commission of Laboratory Accreditation of the College of American Pathologists (CAP) . Stephen J. Sarewitz, MD, FCAP. Recording can be found at **www.cap.org**

2010 NPHL Upcoming events:

Hospital Preparedness CT Training Workshop
Telehealth Broadcasts May 25 and May 27

Nebraska Biological Challenge Set - June

Packaging & Shipping Seminar
Omaha Sept 21 & North Platte Sept 23

Sentinel Laboratory BT Training
Biosafety and Biosecurity Seminar
TBA

Association of Public Health Laboratories (APHL) Upcoming Events:

APHL Annual Meeting and State Environmental Laboratory Conference

Cincinnati, OH - June 6-9, 2010

Omaha, NE - June 5-8, 2011

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Meet the Laboratorian – Dan Griess

Compiled by Karen Stiles MT(ASCP)SM, State Training Coordinator NPHL

What got you interested in pursuing a career in laboratory science?

I have always been fascinated with the sciences. I grew up in Morrill, a small community of 940 people located in Western Nebraska just eight miles from the Wyoming border. My father owned and operated a custom processing plant and I was immersed in the anatomy and physiology of animals, from butchering them on the kill floor to cutting and packaging the numerous cuts of meat, without even knowing the impact this experience would have for me someday. I must admit my science teachers seemed to enjoy my "show and tell" objects such as an occasional eye, or heart, or blood clot to name only a few. Let's just say I kept them guessing.

I happened to read an advertisement from the local junior college that a new program was being introduced into their college curriculum, Medical Laboratory Technician. After reading the article, I made an appointment with the Dean of Eastern Wyoming College in Torrington, Wyoming to learn more about this degree program. My father only attended school through the eighth grade and my mother passed on when I was twelve. As the oldest child, college was a foreign topic in our family and a future career path in healthcare was something I would have never imagined. I believe it was divine intervention.

Where did you attend med tech school? Where did you receive your formal training?

I began my laboratory education by receiving an Associate of Applied Science degree as a Medical Laboratory Technician from Eastern Wyoming College. I chose to continue my education by completing my Bachelor of Science degree in Medical Technology through the University of Nebraska Medical Center, which is also where I completed my student rotations.

How long have you worked in your present location?

After working on the bench for nearly six years in both Scottsbluff and Omaha, I had an opportunity to move into a management position while, at the same time, allowing me to return to Western Nebraska. In March 1992, I accepted the Laboratory Manager position for Box Butte General Hospital in Alliance. Four years later, I moved into a leadership position, Vice President of Support Services, and then assumed the role of Chief Executive Officer at the end of 2003. I have also completed my Master's degree in Healthcare Administration through the University of Minnesota. All in all, I am in my 18th year at Box Butte General Hospital.

What is the biggest challenge you face in your job today?

There are a number of challenges we face in healthcare each and every day. The biggest challenge for me would be related to the topic of workforce. It truly has been a blessing for me to serve in a rural healthcare setting for the past 18 years, both personally and professionally. We have been fortunate to find other health professionals who feel the same way and appreciate the quality of life that rural medicine has to offer. It is a privilege to serve our families and our neighbors in a manner where we are able to promote a patient-centered experience and our patients are cared for by someone they know and they trust. Often, the difficulty lies in our inability to find qualified professionals who exhibit a desire to serve in a rural area. As a small hospital, a vacancy with a Pharmacists, Ultrasonographers or Respiratory Therapists can weaken our ability to offer critical, lifesaving services. Therefore, we work hard to be great at promoting our opportunities when they arise and to give our employees numerous reasons to choose to stay at Box Butte General Hospital.

Additionally, we have partnered with Alliance High School to form a Health Professions Club. These high school students attend monthly meetings at the hospital where they are introduced to a diverse number of health profession careers. Additionally, they must participate in community service activities, job shadowing opportunities and then they are eligible to participate in two field trips to further introduce them to the field of healthcare. We have visited academic programs in Denver, Ft. Collins, Lincoln, Omaha and Rapid City in the past as well as local academic programs offering professional careers through community colleges and satellite college and university campuses. We believe it is important to begin building our workforce locally and at an early age.

(New Recommendations, Continued from page 3)

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