

Delaware LabOrator

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Delaware Public Health Laboratory (DPHL) Biosafety Update

by Gregory Hovan, B.S., M.B.A., Biosafety Official, Delaware Public Health Laboratory

In late May, the Delaware Public Health Laboratory (DPHL) received a call from a Laboratory Manager at a reference laboratory outside of Delaware who expressed concern over a culture that was suspected of harboring *Brucella*.

The term *Brucella* is a generic name referring to any of several different strains of *Brucella* that are in existence. *Brucella*, as such, can cause an infectious disease called Brucellosis. This is a “reportable zoonotic disease” that can spread from animals to humans. In the United States, cases of Brucellosis are rare with approximately 100 cases being reported to the Centers for Disease Control and Prevention (CDC) each year.¹

Among the animals that can harbor *Brucella* are cows, dogs, pigs, sheep, goats, and even camels. Because it is a ‘reportable disease,’ it means that, if found, the organization is required to submit a sample to the State Public Health Laboratory for further identification. Any laboratory that submits this bacteria is required to report and transfer the organism or destroy it within seven days of identification. One reason for this requirement is that the CDC Select Agent Program (SAP) has classified this organism as a potential agent of bioterrorism.



Among the *Brucella* strains, the predominant ones include *Brucella abortus*, *B. melitensis*, and *B. suis*. *B. canis* is much rarer.

Brucella is a small, slow growing, intracellular organism that is difficult to identify using traditional microscopy and gram staining. It is also an organism that, when cultured, can be easily overlooked because of its slow growth rate. Beyond this, it has high pathogenicity and is difficult to

treat. It requires combination antibiotic therapy over a long period of time.¹

When it does occur, transmission is often through the consumption of unpasteurized dairy products or by direct contact with the tissues or bodily fluids from an infected animal. *Brucella* aerosols are considered to be highly infectious, requiring as little as 10-100 bacteria to cause infection (Brucellosis).¹ Brucellosis is the most commonly reported laboratory acquired infection (LAI).

Because the information provided about the patient was not very specific, the Division of Public Health activated personnel and other resources to identify the facility where the person had been seen.

Once identified, the DPHL Biosafety Officer was able to contact them to notify that the patient was suspected of having Brucellosis and to also cease performing any additional laboratory tests or transferring specimens unless the necessary biosafety environment for this type of work was available. These measures would prevent others from being affected.



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The patient had been seen at multiple healthcare facilities with laboratory testing performed in various state jurisdictions. The role of the Biosafety Officer was to coordinate with our partners – including Delaware laboratories - to determine what biosafety procedures were taken and to ensure that the appropriate risk assessments were performed to identify possible personnel exposures. The DPHL worked with Biosafety Officers in other states where laboratory testing had occurred to document facts and to ensure that follow up safety procedures were followed.

As this case was being managed, a separate case was identified as having a presumptive culture with *Brucella*. This patient turned out to be a sibling of the index patient. Through the interviews done by personnel from the DPH Office of Infectious Disease Epidemiology, it was determined that both siblings had consumed unpasteurized cheese that had been imported from Mexico.

Over this time, isolates sent to the Centers for Disease Control (CDC) laboratory also confirmed that this organism was *Brucella melitensis*, which is the most pathogenic *Brucella*.

In the following weeks, additional cases from family members emerged. All told, as of July 31, 2019, there are eight cases, with one case having suspected growth of *Brucella* organism. One case presented with symptoms requiring acute diagnosis over concerns of meningococcal disease. This increased the concerns from our partners and laboratory personnel over potentially spreading *Brucella*. Through additional education and feedback, the Biosafety Officer was able to alleviate concerns and provide guidance on effective methods to test for other infectious agents while providing the appropriate biosafety to reduce possible *Brucella* exposure.

Interesting fact: In 1954, *B. suis* became the first agent weaponized by the United States during its offensive biological warfare program.¹

With increasing ease of global travel and the extensive transfer of products among countries, the possibility of exotic diseases, like *Brucella*, entering the US is increasing. For this reason, the Association of Public Health Laboratories (APHL) has acknowledged the possibility and stated: “As demonstrated by the Ebola and Zika virus outbreaks, it is essential that public health laboratories have the capacity to work safely with high consequence and emerging pathogens and to provide appropriate guidance to clinical laboratories.”

Plans now include extensive outreach efforts to all Delaware healthcare laboratories, as well as private and educational laboratories, to provide educational support and guidance for instances when they may have to work with infectious biological agents.

¹ Laboratory Response Network. *Brucella* Introduction. LRN-1044. 07312018

DPHL promoted Gregory Hovan to the position of Biosafety Officer in April 2019. The position was vacant after the previous incumbent, Marion Fowler, retired after 33 years of service.



May 2019 Laboratory Preparedness Advisory Meeting

by Debra Rutledge, MBA MT(ASCP), BT Laboratory Manager II

The most recent Laboratory Preparedness Advisory Meeting was held at the Delaware Public Health Laboratory on May 19, 2019. These meetings began in 2003 as a requirement for the CDC's National Preparedness Cooperative Agreement to bring laboratory partners together to provide guidance and determine best practices regarding testing algorithms on specimens for agents of bioterrorism. This meeting has evolved to be an opportunity to share common infectious disease needs and concerns with laboratory partners.

Another laboratory requirement for this grant is to provide hands on training to bench microbiologists on recognition and rule out testing for the most common agents of bioterrorism that they may see in patient microbiology cultures in their day to day work. If they are unable to rule out a bioterrorism organism based on the American Society of Microbiology algorithms they are required to send the isolate to our laboratory for further screening and confirmatory testing. Delaware Public Health Laboratory is a member of CDC's Laboratory Response Network, which recently celebrated its twentieth birthday. The LRN is a network of laboratories to respond to biological and chemical threats. They consist of state, federal, military, veterinary, food, and environmental testing laboratories with over 175 laboratories in the United States. More information on the LRN can be found at <https://emergency.cdc.gov/lrn/>

Dr. Doug Riley, veterinarian from the Office of Preparedness, gave an eye opening presentation on One Health. One Health focuses on the concept that one person's health is likely to be interconnected with animals and the environment surrounding them. It encourages everyone to look at the broader picture when evaluating infectious diseases and fosters information sharing across the specialties. More information on One Health can be found at <https://www.cdc.gov/onehealth/>

The next speaker was Sandi Spiegel, Food Safety Manager in Health Systems Protection. Sandi gave a presentation on a success story that was submitted for our Epidemiology and Laboratory Capacity Grant this spring. The story was based on a 2018 road trip that several state employees traveled together for a regional conference with our Food Safety Center of Excellence at Cornell University in Ithaca, New York. A laboratorian, a



DPHL Microbiologists Rebecca Savage and Emma Fare

food outbreak epidemiologist and a food safety inspector were traveling to the conference when a mass flow of emails started flowing from their cell phone email regarding a food establishment food borne outbreak. This continued for the next two hours and as they traveled they decided there needed to be a better means of handling these foodborne outbreak discussions. They decided that conference calls would be initiated with all the key players on a daily basis with a template of the agenda items to discuss. This allows for all players to be able to communicate more effectively and come to a consensus in a timely manner. So far this process has improved the response process to foodborne outbreak investigation.

Theo Hudson, Health Program Coordinator with the Division of Public Health gave a presentation on Sexually Transmitted Infections (STI) statistics in the State of Delaware across different age groups and demographics. STI rates for Delaware remains high, ranked 13th for Chlamydia and 15th for Gonorrhea based on 2017 data from <https://www.alarms.org/std-statistics/>. Theo recommended educating teens on the risks of STI's is the most important thing we can do to help with this problem.

Emily Hanlin, Greg Hovan and Rebecca Savage gave updates on DPHL activities in the past months from a long heavy influenza season, to new tick testing coming our way and sequencing and bioterrorism updates.

DPHL is experiencing a lot of movement with staff moving to different opportunities and retirements. Bear with us as we adjust to these ongoing changes.

Rapid HIV 1/2 Testing in Delaware

by *Fred Franze*, QA Laboratory Manager

IN MARCH 2003, the Division of Public Health (DPH) HIV Program requested that the Delaware Public Health Laboratory (DPHL) provide assistance toward developing and implementing a comprehensive training and quality assurance (QA) program for rapid HIV testing. The Technical Supervisor for DPH Sexually Transmitted Disease clinics was tasked to develop appropriate logs and training materials for the purpose of training personnel.

By June of 2003, the QA program was established and four DPH State Service Centers (SSC) were effectively performing rapid HIV testing. These included Porter SSC (Wilmington), Williams SSC (Dover), Adams SSC (Georgetown) and the Shipley SSC (Seaford). Additionally, the Beautiful Gate Outreach Center, a community based organization in Wilmington, DE, was given permission to start testing in December 2003.

Guidelines from the Centers for Disease Control and Prevention (CDC) became the basis for performing rapid testing (training, QC, etc.). Initial training was provided for Supervisors by the vendor of testing supplies. Supervisors trained other public health staff, as necessary, starting with Laboratory Technicians. Once Laboratory Technicians demonstrated competency in performing the test, clinical staff who would also be involved were also trained.

Training consisted of the following:

1. Overview of test kit contents
2. The requirements for testing (lighting, temperature, work space conditions, etc.).
3. Test set-up protocols (labeling of test device(s), timer requirements, patient preparation, etc.).
4. Quality Control checks and how to resolve any QC failures.
5. Test result interpretation, documentation, and reporting.

After this initial training, staff members were instructed to gain additional experience by practicing the test protocols using QC materials. After two weeks of practice, an on-site follow-up capability evaluation was conducted to verify that staff members are, in fact, capable of performing the test properly with minimal or no assistance. Once verified, permission was granted to test patients.

Initially, the Quality Assurance program consisted of the following:

1. Quality control checks were performed bi-weekly.
2. All trained staff performed QC checks on a rotating basis.
3. All sites were required to participate in the CDC MPEP Proficiency testing program (QC).
4. Sites were to be inspected annually to ensure adherence to DPHL Quality Assurance guidelines and requirements.

Figure 1. Uni-Gold Test



The state used the Oraquick test until October 2007, when DPH transitioned to the Uni-Gold test. In 2014, the State began to use the CDC rapid-rapid test algorithm for Point of Care settings. In this algorithm, an initial positive rapid test is immediately followed by a second rapid test that is provided by a different manufacturer, both being third generation tests.

5. Program managers for the HIV and Title X programs were also trained such that each clearly understood the requirements of the QA program.

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Figure 2. Sure Check Test

From a historic perspective, over the sixteen (16) years in which the Division of Public Health HIV Program has provided rapid HIV 1/2 testing to the citizens of Delaware, many changes and improvements have been made.

The state used the Oraquick® test until October 2007, when DPH transitioned to the Uni-Gold test. In 2014, the State began to use the CDC rapid-rapid test algorithm for Point of Care settings. In this algorithm, an initial positive rapid test is immediately followed by a second rapid test that is provided by a different manufacturer, both being third generation tests. If both tests result as Presumptive Positives, the patient is considered to be a Preliminary Positive for HIV and is referred for follow-up care. DPH uses the Trinity Uni-Gold™ and Chembio Sure Check® rapid HIV test kits for our testing algorithm.

In 2003, the State began work with HIV in four STD clinics and one Community Based Organization (CBO). DPH now supports six SSC clinics, six CBO's, three Westside Health centers, three Planned Parenthood sites, Delaware State University, multiple School Based Wellness Centers, and is in the process of certifying multiple Connections rehabilitation sites.

As expected with the inevitable technical changes in testing and with the expansion of the HIV program to multiple sites, the training program has also had to grow and adapt to meet the needs of service providers.

Notable program changes in the testing program include:

1. With few exceptions, initial training is now provided as an integral part of the HIV program CTR class that is conducted 3-4 times per year.
2. After the initial training is completed, staff are given the opportunity to work with experienced testers to become more proficient.
3. A follow-up visit is conducted by the Program Manager and the DPHL Quality Assurance Manager to ensure continued staff skill and competency.
4. Testing staff have been trained to handle discordant results (one rapid test being presumptive positive with a second test negative).

The Quality Assurance Program has been upgraded to include the following:

1. Quality control checks are performed monthly for established sites (new sites, with no prior experience, are required to perform QC checks bi-weekly until testing personnel are verified to be competent).
2. All trained staff perform QC checks on a rotating basis.
3. All sites are required to participate in an approved Proficiency Testing Program. Currently, the College of American Pathologists or the American College of Physicians (Medical Laboratory Evaluation) are approved vendors.
4. Sites are inspected annually to ensure adherence to DPHL Quality Assurance guidelines and requirements.
5. Program managers for the HIV and Title X programs are trained such that there is understanding of the QA program requirements.

Delaware Public Health Laboratory Drinking Water Section is EPA accredited after triannual inspection that took place on May 6th and 7th 2019.

by Clover Carlisle, Analytical Chemist IV, Environmental Laboratory Manager

EVERY THREE YEARS the Drinking Water Laboratory Section of Delaware Public Health Laboratory (DPHL) is inspected by the Environmental Protection Agency (EPA). The EPA inspection establishes conformity within laboratories. Conformity is established by the use of EPA approved drinking water methods and proper Quality Assurance are being followed in laboratories that are certified to analyze public drinking water for contaminants. Compliant public drinking water samples are analyzed for both Microbiological and Chemical contaminants. Laboratories that are certified provide the public drinking water systems (PWS) with reliable information on the quality of their water. Reported results from laboratories are used to monitor PWS compliance with health-based and aesthetic standards.

For Laboratories to become certified by the EPA to analyze public drinking water samples they must analyze proficiency testing (PT) samples at least annually for each method, including specific analytes, for which they desire certification and pass. Also the laboratories must perform testing by using approved EPA methods, and pass on-site audits either performed by EPA or state certification officer.

The 2019 EPA inspection included certification for chemical and microbiological contaminants. Approved microbiological methods DPHL follows provides results for presence or absence of total coliforms and *Escherichia coli*, quantitation of the same organisms and estimating the number of live, culturable heterotrophic bacteria in water. Approved chemical methods DPHL follows to analyze drinking water



for contaminants include Volatile Organic Compounds (63 compounds both regulated and unregulated), Haloacetic Acids (5 compounds), Anions (Nitrite, Fluoride, Nitrate, Chloride, and Sulfate), Trace Metals (Lead, Mercury, Arsenic, Barium, Beryllium, Copper, Cadmium, Chromium, Selenium, Thallium, Vanadium, Nickel, Antimony, and Uranium), Routine Metals (Sodium, Iron, Hardness), Cyanide, Alkalinity, and Total Dissolved Solids.

Congratulations to the staff in DPHL's Environmental Section of Public Health Laboratory the Delaware for a job well done! The dedicated personnel, notable hard work, and continued Quality Improvements has shown through and once again DPHL is certified to analyze compliant drinking water samples accredited by the EPA.



The Role of Syndromic Surveillance in Public Health

by *Emily E. Hanlin, Epidemiologist II*

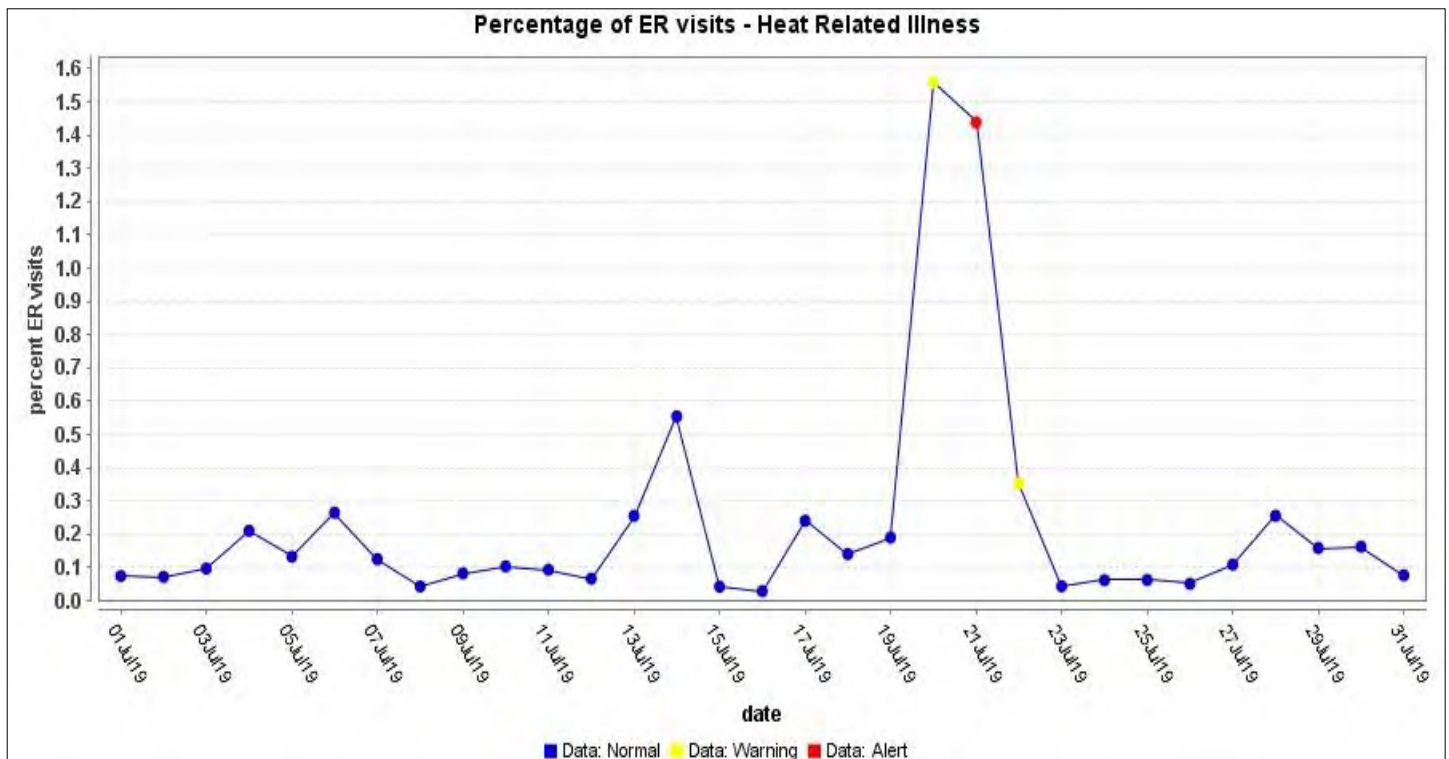
SYNDROMIC SURVEILLANCE refers to the reporting of health indicators, or *syndromes*, prior to a confirmed diagnosis (Mandl et al., 2004). This epidemiological tool evolved in the early 2000's in an effort to respond to and mitigate potential agents of bioterrorism (Mandl et al., 2004). Since then, syndromic surveillance has expanded to an all hazards approach, given the availability of data from the use of Electronic Health Records (EHRs) (Yoon, Ising & Gun, 2017). The Delaware Division of Public Health (DPH) uses the Electronic Surveillance System for the Early Notification of Community Based Epidemics, or ESSENCE. Patient-level data is transmitted electronically in near-real time. Thus, while much of the data is not as specific as individual disease reporting, it is more timely and sensitive (Abat, Chaudet, Rolain, Colson & Raoult, 2016). Delaware's ESSENCE information is received from all Emergency Departments (EDs) around the state, and includes school absenteeism information, and number of students with Influenza Like Illness (ILI) reported by school nurses. ED information is categorized by chief complaints, e.g., why the patient visited the ED. Chief complaints include 12 syndromes in ESSENCE: Botulism like illness, expo-

sure, fever, gastrointestinal, hemorrhagic illness, ILI, injury, neurological, rash, respiratory, shock/coma, and records of interest (usually notifiable diseases). Moreover, additional subsyndromes can be queried (e.g. – bite or sting, fetal death, or motor vehicle accident), as well as discharge information, and advanced queries designed to capture specific information or events.

ESSENCE uses Exponentially Weighted Moving Average (EWMA) statistical analysis as its default. EWMA utilizes linear regression to compare current data trends with historical data trends, weighting current trends more heavily. This allows for alerts which are easily color coded for the user to see: red = data alert, yellow = data warning, and blue = normal data. Figure 3 demonstrates ESSENCE time series data for an advanced query designed for "Heat Related Illness," and shows elevations in ED visits during a recent heatwave in July 2019.

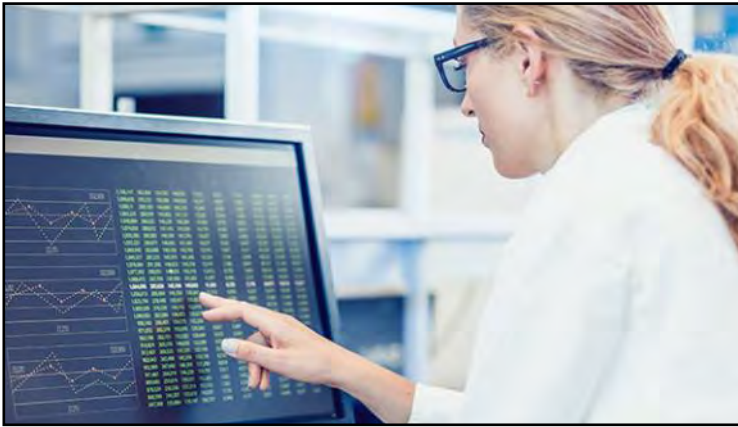
Stratifying the information by age demonstrates that the highest percentage of ED visits during the July 2019 heatwave were from individuals ages 5-17 and 18-44.

Figure 3. Percentage of Emergency Department visits, Heat-Related Illness, Delaware, July 2019.



Source: ESSENCE

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While syndromic surveillance provides valuable information, it should be coupled with other epidemiological tools. (Abat et al., 2016). For instance, the health burden of an influenza season can be assessed by obtaining ILI information from ESSENCE and confirmed cases through the Delaware Electronic Surveillance System (DERSS). With technology constantly expanding, public health threats and emerging infectious diseases will become identified more quickly (Abat et al., 2016). This proactive

approach will lead to earlier mitigation and necessary policy changes (Abat et al., 2016).

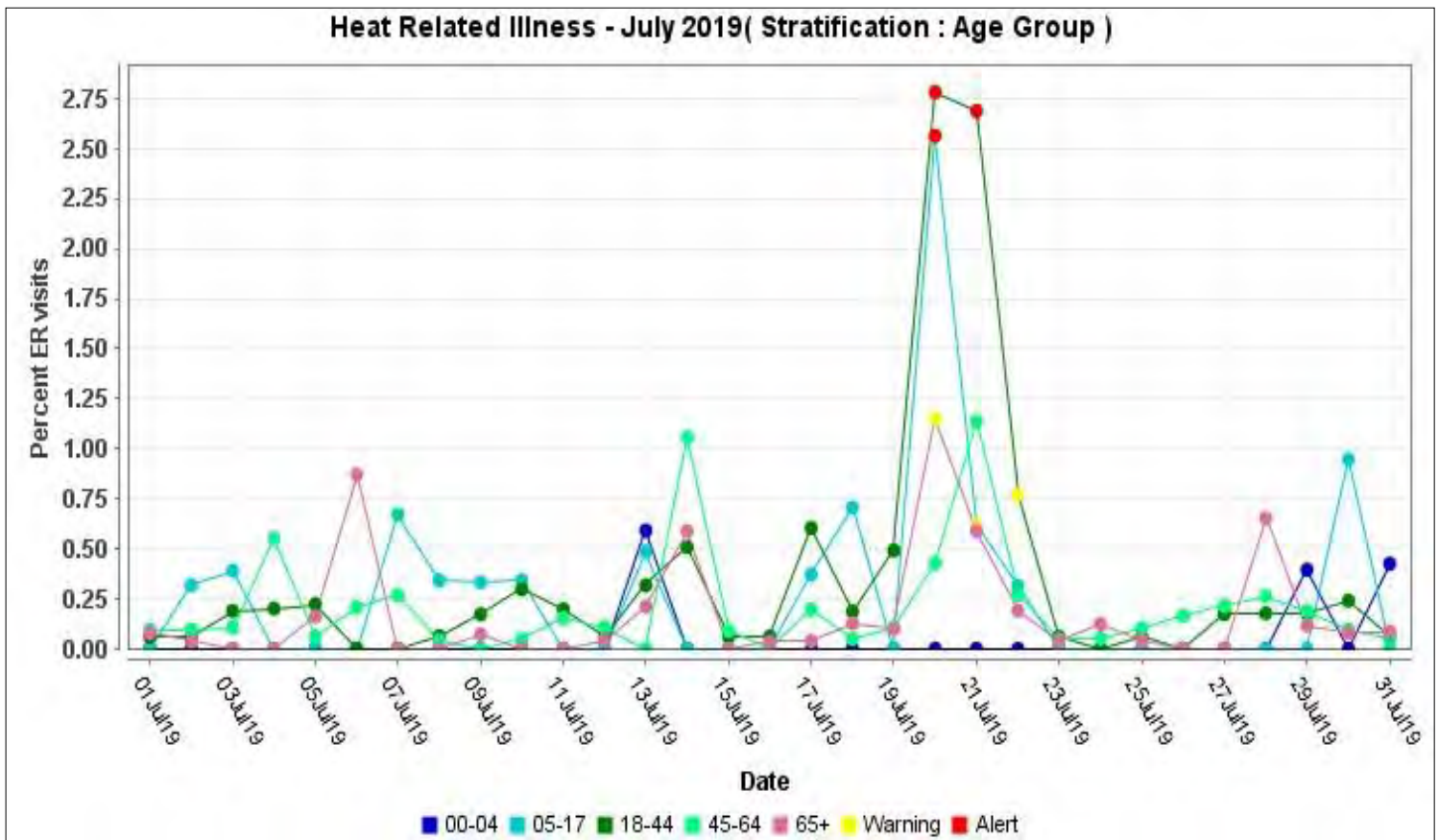
References:

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Yoon, P. W., Ising, A. I., & Gunn, J. E. Using Syndromic Surveillance for All-Hazards Public Health Surveillance: Successes, Challenges, and the Future. *Public Health Reports*, 132(1 Suppl), 3S-6S. doi: 10.1177%2F0033354917708995

Figure 4. Percentage of Emergency Department visits, Heat-Related Illness, Delaware, July 2019.



Source: ESSENCE

EMPLOYEE NEWS

Congratulations, Greg!

Gregory Hovan. Greg has accepted a position at the laboratory as our new Biosafety Official. Greg has worked for the Public Health Laboratory since accepting a contract microbiologist in February of 2009. He was later promoted to a merit position as a microbiologist, eventually becoming the Laboratory Manager, a position held for the past seven years. Greg has an undergrad in Biochemistry and a Master's in Business Administration. He has been married to his lovely wife Cynthia for nine years, with three lovely daughters, Olivia, seven, Eva, five, and Veronica, two. Greg and his family reside in Sussex County equal distances from beach and farm with several cats and a Labrador. Besides his family and work, he enjoys sports, music, and outdoor activities



Congratulations, Jerry!



Jerry Clark. DPHL congratulates Jerry on his promotion to Office Manager. He started with the lab in November of 2017 as an Operations Support Specialist and was promoted to Administrative Specialist III in April of 2018. Jerry comes from an extensive background in educational publishing, customer service, and administrative support. He enjoys traveling, cooking, outdoor music festivals, and spending time with family. Jerry is a recreational Texas Hold'em player and has self-published two books on the subject.

Welcome, Jason!

Jason deYoung. DPHL welcomes Jason as the new contract Lab Technician. Jason joined the administration team of the Delaware Public Health Laboratory in April of 2019. He received his associates degree in Biotechnology from Delaware technical and community college and continued his studies at Delaware State University to receive his Bachelor's degree. Jason is engaged and his fiancé and he are planning to get married in 2020.



Welcome, Craig!

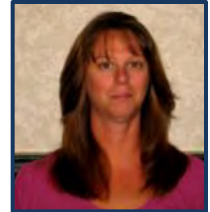


Craig Walker. DPHL welcomes Craig as the new contract LIMS Assistant Administrator. Craig has a BA degree in chemistry from Cheyney State college. He comes from Teligent Inc.: where, he configured and validated the Nova-tech LIMS (Laboratory Information management System) system for their QC lab. Craig has over twenty years' experience with LIMS in the Pharmaceutical industry. He and his wife have 4 children. Craig enjoys motorcycling and Photography

EMPLOYEE NEWS *(continued)*

Welcome, Teresa!

Teresa Reed. DPHL welcomes Teresa as the new Management Analyst II. She comes to us from DPH's Emergency Medical Services and Preparedness Section (EMSPS), where she has 9 years' experience as the Office Manager and 11 total years with Public Health. During her time with EMSPS she was instrumental in the operation of the State Health Operation Center (SHOC). Prior to coming to the State, Teresa spent 14 years with Oriole Chemical Carriers in Delaware City as an Accounts Receivable Billing Clerk. Teresa enjoys spending time with her family (especially her four grandchildren,) road trips and softball.



Congratulations, Randy!



Randy Correia. Randy has accepted a new position in DPHL as the Supply, Storage and Distribution Supervisor. He has been with the laboratory since August of 2016 holding the positions of Supply, Storage and Distribution Technician I and Environmental Control Technician II. Prior to joining DPHL, Randy worked for Walmart as a Regional Compliance Manager. He retired from the Air Force Reserve after 30 years of service. Randy has a Masters degree in Human Resource Management from Wilmington University. He lives in the Felton area with his wife and three children.

Farewell, Emily!

Emily Hanlin left DPHL after 10 years as Laboratory Manager of the Molecular Virology section. She has since accepted an Epidemiologist position within DPH's Office of Preparedness. Emily is obtaining her Master of Public Health degree from Des Moines University of Osteopathic Medicine. She looks forward to blending her scientific background with her epidemiological study and endeavors. Emily notes that she has almost no spare time in between work and school, but still enjoys spending time with her family and running when she can.

