Arizona Department of Health Services

State Public Health Laboratory

Sentinel Newsletter

September 2013

Welcome to the Arizona Department of Health Service (ADHS) State Public Health Laboratory's Newsletter. This biannual publication will provide information on upcoming events, current projects and any changes or update with laboratory services,.

If there is something you would like to see addressed in the future on content you would like to submit, please contact Heather Matthies, ADHS State Training Coordinator at Heather.Matthies@azdhs.gov. Thanks!

Save the Date!

"Packaging & Shipping of Infectious Substances Training Course"

Click on the Link

- Tucson 10.28.2013
- Phoenix 10.30.2013

New Faces at ASPHL!

Hello! I am very excited and honored to have the opportunity to write the introduction to the Arizona State Public Health Laboratory (ASPHL) newsletter! There have been quite a few changes at the ASPHL recently. **We have a new Laboratory Training Coordinator, Heather Matthies.** Heather is joining us from Arizona State University where she worked extensively in a variety scientific research.

In This Edition

Now that she is with ASPHL, she will be responsible for carrying out our external and internal training projects, including arranging Division 6.2 packing and shipping training and rule out and refer testing training. She's also the primary editor for this newsletter!

We also have a new Responsible Official and Laboratory Chief of Biosafety, Joe Manfrida (that's me!). My duties include acting as the primary contact at the ASPHL for the federal Select Agent program, writing, maintaining and carrying out the ASPHL's safety plans, organizing and directing the Laboratory's outreach program to the Laboratory Response Network, and developing new ways to communicate and assist Arizona's sentinel clinical laboratories and our associate clinical labs.

This newsletter represents one of our initiatives to increase our ability to share information and opportunities with you, our Arizona public health partners. We will be sending you a newsletter twice annually. In the newsletter you will find announcements about upcoming training opportunities, notices for clinical labs from the CDC and ASPHL, as well as informative and entertaining essays on a variety of public health topics.

This addition has several articles. Heather has written brief articles about how to qualify as a sentinel clinical lab under the new October 2012 definition from the CDC, as well as an overview article about MERS-CoV. If you're looking for something with a little more depth, I have also written a short essay comparing H7N9 and H5N1 influenza, and the implications of the similarities and differences between

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LRN LABORATORY RESPONSE NETWORK

New Faces at ASPHL cont. from p.1

these two virus strains for public health activities. In the future we hope to include articles from other contributors.

It is my sincerest wish that you find this newsletter to be an interesting addition to our communications. Heather and I welcome your suggestions. Please feel free to contact us by email, we look forward to hearing from you!

Best regards!

Joe

Joseph Manfrida, Responsible Official and Laboratory Chief of Biosafety
(joseph.manfrida@azdhs.gov)

Heather Matthies, Laboratory Training Coordinator
(Heather.Matthies@azdhs.gov)

2013 LRN Sentinel Lab Call Down Drill Report

The ASPHL conducts Call Down drills to measure our ability to send emergency messages through our computerized emergency contact system, AZHAN. When activated, AZHAN contacts all sentinel clinical labs through email and automated telephone calls. Upon receipt of the message, the contacted sentinel clinical lab replies to AZHAN to ensure that the message was received. In an ideal situation, all sentinel labs will respond to the alert message.

Our first drill this year was conducted on **February 27th, 2013. 55%** of the sentinel labs responded to the alert message. An internal investigation into the low response rate found that the database being used for the contact drill had not been updated for over six months. Many of the failures to reply to the emergency message could be attributed to outdated contact information or contacting labs that no longer qualified as sentinel clinical labs under the October 2012 definition released by the CDC. An extensive review and update of the laboratory database was initiated to correct these problems.

A second drill was conducted on **June 26th, 2013**, after significant effort had been spent updating the database of laboratory contact information. In this drill **90%** of the sentinel clinical labs responded to the alert message. A post-drill investigation revealed that labs who did not respond to the drill had inadvertently provided the ASPHL with contact numbers that would not work over a 24 hour period. Alternate contact information was obtained which will work 24/7.

The ASPHL will continue to conduct Call Down drills in the future. Additionally, the database review and update project has been made an ongoing process to ensure that the ASPHL always has access to the most recent contact information for all sentinel clinical laboratories and associated public health partners.

Call Down Drill Date	% Response	Comment	Corrective Action
February 27th 2013	55%	Low response. Due primarily to outdated list of Sentinel Lab contacts	Updated database
June 26th 2013	90%	Evaluation found contact number were not 24hr accessible	Changed contact numbers to those that are answered 24/7

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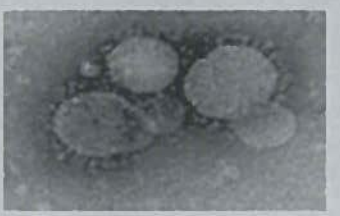
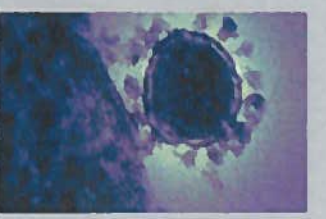
LRN LABORATORY RESPONSE NETWORK

Middle East Respiratory Syndrome Coronavirus (MERS-CoV)

Heather Matthies





What Is MERS-CoV ?

Middle East Respiratory Syndrome (MERS) was first reported in Saudi Arabia in 2012 and characterized by Dr. Ali Mohamed Zaki as a previously unknown and novel coronavirus now designated MERS-CoV. [1]

Genetic sequence analyses have shown that this new virus is different from any other known human coronaviruses, including the one that caused severe acute respiratory syndrome (SARS).[2]

Cases to Date of MERS-CoV

Most people who have been confirmed to have MERS-CoV infection developed severe acute respiratory illness with the symptoms of fever, cough, and shortness of breath. About half of these people died. One cluster that occurred within a family in the UK provides the first clear evidence that human to human transmission does occur with this disease.[2]

Currently, cases have been linked to four countries in or near the Arabian Peninsula (Saudi Arabia, Jordan, Qatar & UAE). Other outbreaks have occurred in Northern Africa, France Italy and the United Kingdom. All countries other than the Middle East had had cases that had recently traveled there. No cases have been identified in the U.S.[2]

MERS Cases & Deaths from April 2012 – Sep 19, 2013

Countries	Cases (Deaths)
France	2 (1)
Italy	1 (0)
Jordan	2 (2)
Qatar	5 (3)
Saudi Arabia	108 (47)
Tunisia	3 (1)
United Kingdom (UK)	3 (2)
United Arab Emirates (UAE)	6 (2)
Total	130 (58)

CDC http://www.cdc.gov/coronavirus/mers/

Potential Sources in Arizona

For Arizona (and in the rest of the country) one potential source for a MERS-CoV outbreak that health care workers should be on the watch out for is from the large population of International students, many of whom come from the Middle East, who will be returning to classes in the fall at the State's Universities. With many students living together in dorms and apartments as well as being confined together in classrooms, close contact among students creates the potential for human to human transmission if an infected person is present. Educational outreach to University clinics and health care workers will be an important measure.

Millions Traveling to Saudi Arabia in October

Another source of MERS-CoV could come later in the fall/winter as travelers return from the Middle East's largest pilgrimage at The Hajj. The Hajj pilgrimage occurs each year in Mecca, Saudi Arabia where the majority of the cases occurred last year.

The Hajj will occur in mid-October but pilgrims will often arrive as early as September and stay as long as November. Very large crowds will be in close proximity during this time not only for events surrounding The Hajj but also living together in tent communities and hotels in the surrounding area. The Saudi Foreign embassy estimated that the number of Pilgrims who attended in 2012 to be 3.2 Million.[3]

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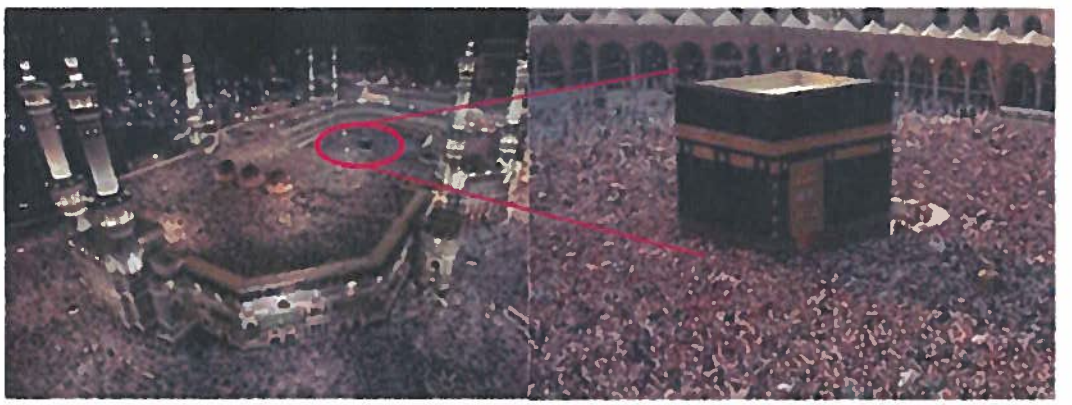

The Hajj in Mecca, Saudi Arabia saw 3.2 Million pilgrims in 2012 [3,4]

MERS-CoV cont. from p.3

What to Watch For & How to Respond

Both the CDC and WHO advise health care workers to maintain vigilance regarding persons who develop severe acute lower respiratory illness within 10 days after traveling from the Arabian Peninsula or neighboring countries. These persons should continue to be evaluated according to current guidelines and practices. However, if they do not respond to appropriate therapy may be considered for evaluation for novel coronavirus infection.[5,6]

Importantly, Arizona State Public Health Laboratory passed all the requirements to test for the new virus under an Emergency Use Authorization[7] from the FDA and received the CDC-developed assay test kit from the Laboratory Response Network making the lab able to test any suspect patient samples in Arizona without having to spend additional time sending samples to the CDC and waiting for results.

To report potential MERS cases to the CDC by filling out the Middle East Respiratory Syndrome (MERS) Patient Under Investigation (PUI) Short form. http://www.cdc.gov/coronavirus/mers/downloads/MERS-investigation-short-form.pdf

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What Does It Mean To Be A Sentinel Lab As Part Of The Laboratory Response Network?

Heather Matthies

The Laboratory Response Network (LRN) was established by the Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), the Federal Bureau of Investigations (FBI) and Association of Public Health Laboratories (APHL) to function as a collaborative unit during any sort of national emergency.

The LRN is charged with the task of maintaining an integrated network of state and local public health, federal, military, and international laboratories that can quickly respond to bioterrorism, chemical terrorism, naturally occurring outbreaks and other high priority public health emergencies needs through training, rapid testing, timely notification and secure messaging of laboratory results.

We at the Arizona Department of Health Safety State Laboratory want to do everything we can to make sure that our state is prepared in the case of an emergency, disease outbreak or terrorist attack.

One way the DHS State Laboratory tries to help with emergency preparedness is to offer assistance and training to all laboratories in the state that are capable of analyzing or referring specimens that may contain potential bioterrorism organisms known as Select Agents.

Recent changes in the requirements in what is needed to be a Sentinel laboratory are requiring the State Lab to reorganize our contact lists of the labs in the state who can safely and effectively be Sentinel Laboratories.

As a Laboratory Professional ask yourself these questions:

- Are you familiar with what a Select Bioterrorist Agent is?
- How likely will your lab see a Select Bioterrorist Agent (in AZ some are endemic)?
- Do you know how and when your lab needs to refer diagnostic specimens or isolates that are suspected to contain agents that are of serious public health significance to the State Public Health Laboratory?
- Are you familiar with the reportable disease guidelines for Arizona?
- Can your lab safely and legally package and ship an infectious substance or Select Agent?
- Would you lab like to learn more about the rules and regulations of the Select Agent Program?

What is a Select Agent?

A Select Agent is any pathogen or biological toxin that has been declared by the **U.S. Department of Health and Human Services** (HHS/CDC) and by the **U.S. Department of Agriculture** (USDA) to have the potential to pose a severe threat to *Public Health, Safety & the Economy*. The CDC Select Agent Program regulates the possession, use, and transfer of biological agents and toxins that could pose a severe threat to public health and safety.

To see a complete listing of Select Agents go to the CDC website at: http://www.selectagents.gov/select%20agents%20and%20toxins%20list.html

Why become a Sentinel Laboratory and work with the State Public Health Laboratory as part of the Laboratory Response Network?

Hospitals, environmental, food, veterinary, agriculture, military and clinical laboratories already routinely test patient, animal and environmental samples and provide timely results for patient care *so why would you want to add to your responsibilities?*

Answer

- As a Sentinel Lab you would have access to information, training and updates not always available to nonparticipating labs in the state.
- You would be part of a network that will keep you informed about surveillance and responses to endemic and emerging pathogens, including identification of novel threats such as pandemic influenza and vaccine availability
- Be on the inside track regarding Bioterrorist Select Agents and natural outbreaks of Select Agent events both locally and nationally.
- *Free* access to specialized training on how to safely handle and report Select Agents
- *Free* access to training on the Packaging & Shipping of Infectious & Select Agents
- *Free* access to specialized Webinars hosted by the DHS.
- Continuing Education Credits (CEU) for are available for those who require them for their licenses.
- Participation in Emergency Response Exercises that better prepare your facility in the event of a disaster or terrorist attack.

What are the Requirements to be a Sentinel Laboratory?

Any lab capable of analyzing or referring specimens or samples that may contain microbial agents or toxins can operate as a Sentinel Lab if they meet additional requirements that are needed for Select Agents found in nature and that would be of interest to Bioterrorists

Answer

Responsibilities of the Sentinel Clinical Laboratory

1. The laboratory is *familiar with reportable disease guidelines in its jurisdiction*, and has *policies and procedures in place* to refer diagnostic specimens or isolates suspected to contain agents of public health significance to the local or state public health laboratory in its jurisdiction.
2. The laboratory ensures personnel have met the applicable federal regulations for *packing and shipping of infectious substances.*
3. The laboratory has policies and procedures for referral of suspected Bioterrorist Select Agent, specimens and/or isolates to the LRN Reference Laboratory in its jurisdiction that reflect the *American Society for Microbiology (*ASM) *Sentinel Level Clinical Microbiology Laboratory Guidelines for Suspected Agents of Bioterrorism and Emerging Infectious Diseases* available for download on the ASM website at http://www.asm.org/index.php/policy/sentinel-level-clinical-microbiology-laboratory-guidelines.html

4. The laboratory *maintains the capability* to perform testing outlined in the ASM *Sentinel Level Clinical Microbiology Laboratory Guidelines for Suspected Agents of Bioterrorism and Emerging Infectious Diseases* and demonstrates annual competency by participation in proficiency testing or exercises, such as the Laboratory Preparedness Exercise. (http://www.asm.org/index.php/guidelines/sentinel-guidelines)
5. The laboratory has a Class II or higher Certified Biological Safety Cabinet.
6. The laboratory complies with Biosafety Level II (BSL-2) practices as outlined in the current edition of the *Biosafety in Microbiological and Biomedical Laboratories* guidelines.
7. The laboratory complies with applicable Occupational Safety and Health Administration (OSHA) regulations for a respiratory protection program such as N-95 or P-100 fit testing. (https://www.osha.gov/Publications/osha3079.pdf).
8. The laboratory complies with the rules and regulations of the Select Agent Program
9. The laboratory participates in the Laboratory Preparedness Exercise (LPX) proficiency tests for participating APHL/LRN Sentinel Labs to "rule out and refer" select agents. There are 3 performed each year and are provided by the College of American Pathologists (CAP).

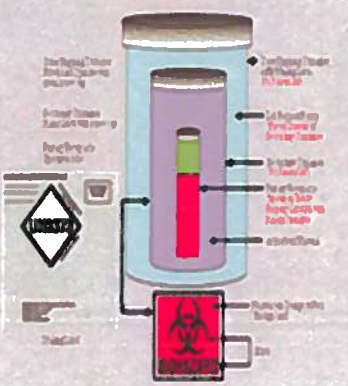
What do I need to do to become a Sentinel Laboratory?

It's easy!

If you think you meet the requirements listed above then simply send us the following information:

- Laboratory Name, Address & CLIA number
- Primary & Secondary contact Information (Name, Title, Email, Phone, Fax)
- 24/7 emergency Contact (Phone/Pager/Answering Service)
- The best method to receive emergency alerts and communications (e.g. Email or Phone)
- Register to participate in the College of American Pathologists LPX proficiency test (contact us to assist you with this process)

Please send your information to:
Heather.Matthies@azdhs.gov or call (602)542-6175



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A Brief Comparison of H5N1 and H7N9 Avian Influenza and its Implications for Public Health Interventions

By Joseph P. Manfrida, PhD, Responsible Official and Lab Chief of Biosafety and Biosecurity, Arizona Department of Health Services Public Health Lab

In March of 2013, the Chinese Center for Disease Control and Prevention (China CDC) initially reported the identification of a novel strain of H7N9 influenza virus in humans. By April 29, 2013, this new strain had been confirmed as having caused 126 illnesses with a 19% fatality rate.[1] The obvious public health threat posed by this novel strain quickly caught the attention of public health officials and scientists. The efforts of these individuals has produced a significant body of data which can be compared to what is currently known about a similar strain of influenza, H5N1, in order to make inferences about what we can expect from this new strain and how public health agencies may be able to most effectively respond to it.

There are marked similarities in the epidemiology of H5N1 and H7N9 influenza. Both strains were first identified in China, H5N1 in 1997 and H7N9 in 2013.[1, 2] The primary viral reservoir consists of birds, particularly domesticated chickens and ducks, but there is indication that wild birds are capable of being infected and spreading both influenza strains. Out of 68,060 animal specimens tested for H7N9 infection, 46 tested positive, and all of the positive specimens were from birds.[3] Likewise, the spread of H5N1 from China to Japan, South Korea, Europe and Africa appears to have been the result of migratory wild duck populations.[4] Both H5N1 and H7N9 infections in humans arose among populations of individuals working in the poultry production industry, raising, transporting or slaughtering live chickens and ducks. Transmission of the virus from one human to another is very limited and generally appears to occur only when individuals are in close proximity with an infected person for protracted periods of time, as occurs with family members or health care providers. Family clusters of infections have been recorded for both H5N1 and H7N9, but the furthest recorded spread of the disease has not exceeded three generations of infected individuals (from a poultry worker to another individual, who then infects a third individual).[1, 2]

Given the similarities in the infectious patterns of these two strains of influenza, it is likely that the geographic and temporal spread of H7N9 will follow a pattern similar to that of H5N1. Over the past 16 years, H5N1 has spread from China to 15 different countries and has become endemic in six countries (Bangladesh, China, Egypt, India, Indonesia and Vietnam.)[2] Outbreaks of H5N1 typically occur during the cooler months of the year, which also corresponds with outbreaks in poultry populations.[5]

Similarly, H7N9 cases initially appeared in the cool months of spring in 2013 and have been confirmed in 8 provinces of China over a five month period.[6] Given time, H7N9 will likely spread to the same countries as H5N1 and become endemic as well. It remains to be seen if this prediction actually comes to pass.

There are significant differences in the pathogenicity of these two influenza strains which may complicate efforts by public health officials to delay the spread of H7N9 using the techniques developed to combat H5N1. Pathogenicity in H5N1 and H7N9 show a marked difference in both poultry and humans. H5N1 is classified as High Pathogenicity Avian Influenza (HPAI). Chickens infected with H5N1 become symptomatic and die within 3 to 6 days after infection. H7N9 is classified as Low Pathogenicity Avian Influenza (LPAI). H7N9 infections in chickens are typically subclinical and rarely cause death.[7] However, it must be understood that the high versus low pathogenicity referred to in these designations strictly reflects the strains' pathogenicity in chickens and not humans. In humans both virus strains can be fatal, though at different fatality rates (60% for H5N1 and 19% for H7N9).[1, 2] These differences are significant when taken in the context of the public health measures which have demonstrated effectiveness in countries with endemic H5N1.

The most effective efforts to combat the spread of H5N1 have focused on the poultry production and transportation system. These techniques seek to halt the spread of the virus by preventing it from being transmitted from wild birds to poultry, from live poultry to other live poultry, and from poultry to humans. Prior to the outbreak of H5N1 in China, the majority of poultry was produced on "backyard" farms where chickens or ducks were raised in pens open to the outside environment which allowed for easy interaction between wild birds and domesticated poultry, providing opportunities for the virus to be spread. Poultry was transferred to live markets where they were kept in pens until slaughtered. The slaughtering of infected chickens generated aerosols containing the virus which then was inhaled by both humans and uninfected chickens alike. Chickens which were not purchased and slaughtered at the market were sometimes taken back to farms where they could infect the rest of the flock.[4]

Chinese authorities focused on breaking up this chain of events to reduce the spread of the virus. Flocks of chickens were examined for the virus. Those exhibiting signs of infection were destroyed, and uninfected flocks were vaccinated. Vaccination prevents H5N1 deaths and greatly reduces the shedding of virus from animals that become infected, thereby reducing the likelihood of a sick bird infecting another. The live poultry markets were subjected to extensive decontamination to eliminate the virus on surfaces and in pens during mandatory "rest days" where the market was shut down. This helped to prevent infection by removing or inactivating the H5N1 virus on surfaces, which is very important given that the influenza virus has been demonstrated to be resistant to drying and can remain infectious for up to two weeks on a dry surface.[7]

The combination of vaccination and increased market and supply system cleanliness has successfully contributed to the elimination of H5N1 outbreaks from the developed areas of China since 2009.[4]. A contributing factor to the removal of the H5N1 virus in developed areas of China is the replacement of "backyard" farming techniques with large poultry production companies which are better able to enforce improved standards of hygiene in transportation systems and markets as well as increased biosecurity (isolation) of flocks from wild bird populations and domesticated flocks known to be infected.[4]

The techniques used by Chinese public health officials have two significant drawbacks. First, the extensive examination of poultry flocks, vaccination programs, hygiene programs and record keeping for maintaining surveillance of the virus is expensive. Rural areas of China and less developed nations do not have the infrastructure, experience or resources to successfully carry out a wide spread, multi – element public health program for a single disease. Countries with limited resources are forced to divide their efforts between multiple programs, and the political will is largely insufficient to dedicate enough resources to completely eradicate avian influenza viruses from those nations where they are endemic. Second, the types of surveillance used to track flocks infected with H5N1 influenza will not work with H7N9 influenza. Recall that H5N1 is HPAI, and H7N9 is LPAI. The veterinary examinations which can detect infection in a flock exposed to H5N1 look for signs of the disease being expressed as symptoms. However, as indicated earlier, H7N9 is subclinical in chickens. A routine veterinary examination will not detect H7N9 in an infected bird as there are no symptoms exhibited to detect. Viral infections can be detected by serology. An infected bird will produce antibodies specific to the virus that infects it. However, a bird vaccinated against influenza virus will also produce antibodies which react in the same manner as those produced by an infected animal to serology tests. As a result, vaccinated birds produce identical results to infected birds in currently available serology tests.[4] This presents a distinct conundrum for public health officials attempting to implement influenza control programs. If a bird at a market tests positive for H7N9, does this indicate that a flock has been infected, or does it indicate that a bird has been vaccinated? Without excellent record keeping and a scrupulously honest population of poultry workers, this would be impossible to determine, making the isolation and destruction of infected flocks effectively impossible for H7N9.

Public health interventions which have worked for H5N1 have the potential to work with H7N9 as well if certain criteria can be met. Resources must be made available to implement procedures in both developed areas and rural areas, and the political will must be generated in local populations to cooperate with the public health activities. Additionally, a means of distinguishing infected birds from vaccinated ones which is quick and accurate must be developed so that infected flocks can be isolated and destroyed. If these conditions can be met in all of the areas where H5N1 and H7N9 influenza are currently endemic, then it is likely that these viruses can be eliminated from populated areas and contained to rural wild bird populations.

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