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Non-tuberculous Mycobacterium (NTM) Infections and Heater-Cooler Devices used During Surgeries and Other Medical Procedures

The Centers for Disease Control and Prevention (CDC) has identified a need for increased awareness about health care-associated Non-tuberculous Mycobacterium (NTM) infections through health departments, healthcare facilities, and individual healthcare providers. The U.S. Food and Drug Administration (FDA) recently issued a Safety Communication on NTM associated with heatercooler devices that addresses concerns regarding the correct use and maintenance. The CDC has collaborated with the FDA and local and state health departments to





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investigate heater-cooler units associated with NTM infections and/or found to be contaminated with NTM.

Heater-cooler devices are frequently used during cardiac surgical procedures to warm and cool a patient's blood during cardiopulmonary bypass. NTM are slow-growing bacteria found in surface water, tap water, and soil. Recent reports have suggested a relationship between heatercooler devices and NTM infections among patients undergoing cardiac surgery potentially through the aerosolization of bacteria from contaminated water used in these devices.¹⁻⁴ The most important action to protect patients is to remove contaminated heater-coolers from operating rooms, and ensure those in service are correctly maintained.

Patients who might have been exposed to NTM during a surgical procedure should continue to look for signs of potential infection and keep in touch with their clinicians for further evaluation. Due to the potentially long delay between exposure to NTM and manifestation of clinical infection (up to several years), identifying infections related to the use of heater-cooler devices can be challenging.

Recommendations for Healthcare Facilities:

Immediately assess the heater-cooler units and confirm their safety and maintenance. Clinical staff should maintain heightened awareness for possible NTM infections in patients who have had cardiac surgical procedures involving the use of heater-cooler devices.

Actions healthcare facilities should consider include:

- Ensure the facility is following the most current manufacturer's instructions and FDA's recommendations for maintenance, cleaning, disinfection and monitoring of heater-cooler devices.
- If a heater-cooler device in the facility tests positive for NTM or if there is concern for patient infections related to the heater-cooler device, review the facility's

microbiological database and records of surgical procedures to identify any patients that have had NTM-positive cultures within four years following a cardiac surgery procedure.

If a heater-cooler device is suspected to have led to patient infections or if it has tested positive for NTM, promptly
notify your county health department, submit a report to FDA via MedWatch, and assess the need for notifying
exposed patients in coordination with public health authorities.

Recommendations for Healthcare Providers:

Healthcare providers should have increased suspicion for NTM infections among patients who have signs of infection and a history of cardiac surgery. Actions to consider include:

- Assessment for NTM infection for patients who report signs or symptoms of infection and who have undergone cardiac surgery within the previous four years.
- Patients suspected to have an NTM infection should be assessed for a history of cardiac surgery or exposure to a heater-cooler device. Other healthcare exposures such as injections, plastic surgery, and dialysis may also be associated with NTM infections and warrant consultation with public health authorities or reporting to FDA.
- Order mycobacterial culture in patients who have undergone a cardiac procedure within the previous four years who present signs of infection.
 - Patients with NTM infections following cardiac surgery have presented with a variety of clinical manifestations. Common examples include endocarditis, surgical site infection, and bacteremia. However, other clinical manifestations have included hepatitis, splenomegaly, and osteomyelitis.
 - Diagnosis can be difficult due to the non-specific presentation of illness, but it is important that providers maintain an index of suspicion in patients with a history of cardiac surgery. Consider arranging consultation with an infectious disease specialist. It is also important to obtain acid fast bacteria (AFB) cultures to increase the likelihood of identification of the organism as well as to obtain an AFB smear in order to have preliminary information while awaiting culture results.

Recommendations for Patients:

Patients who have recently had cardiac or thoracic surgery should contact their health care provider if they have (a) symptoms of NTM infection, which may include a combination of the following: fever; pain, redness, heat, or pus around a surgical incision; night sweats; joint pain; muscle pain; and fatigue; or (b) questions about possible or exposure to a heater-cooler device. It is important to note that these infections typically develop slowly and treatment may not be needed right away. Those who were exposed to NTM should continue to look for signs of unexplained infection and keep in touch with their health care professionals for further evaluation and tracking.

References:

- 1. U.S. Food and Drug Administration, Nontuberculous Mycobacterium Infections Associated with Heater-Cooler Devices: FDA Safety Communication: October 15, 2015.
- 2. Kohler P, Kuster SP, Bloemberg G, et al. Healthcare-associated prosthetic heart valve, aortic vascular graft, and disseminated Mycobacterium chimaera infections subsequent to open heart surgery. European heart journal. Jul 17 2015.
- 3. Sax H, Bloemberg G, Hasse B, et al. Prolonged Outbreak of Mycobacterium chimaera Infection After Open-Chest Heart Surgery. Clinical infectious diseases: an official publication of the Infectious Diseases Society of America. Jul 1 2015;61(1):67-75.
- 4. Mycobacterial infections associated with heater cooler units used in cardiac surgery: advice for providers of cardiac surgery. London: Public Health England; 2015.

Influenza Surveillance

Local: Seminole County is reporting **MILD** flu activity for the month of October. No **influenza outbreaks** have been reported in Seminole for the 2015-2016. The ESSENCE Syndromic Surveillance system is showing increasing influenza-like illness (ILI) chief complaints.

State: Florida is currently reporting **SPORADIC** flu activity. Influenza activity has slightly **INCREASED** in recent weeks. **One (1) influenza or ILI outbreak** has been reported this flu season. The preliminary estimated number of deaths due to pneumonia and influenza in Florida is similar to levels seen in previous years at this time. In week 42, 22 specimens were submitted to BPHL for influenza testing and one (4.5%) was PCR positive for influenza A not yet subtyped.

National: MILD levels of flu activity are being reported nationwide. The predominantly circulating strain in recent weeks has shifted from influenza B to influenza A (H3), which is typical for this time of year. Additional information can be found at the following link: http://emergency.cdc.gov/han/han00374.asp



Arbovirus Surveillance

Seminole County Mosquito-borne Illness Statistics 2015 Year to Date:

West Nile Virus: 10 Sentinel Chicken

Eastern Equine Encephalitis: 4 Sentinel Chickens

St. Louis Encephalitis: 1 Sentinel Chicken

Dengue: 1 human imported case

Chikungunya: 3 human imported cases

Malaria: N/A



Gastrointestinal Illness Surveillance

Gastrointestinal Illness typically follows a trend similar to influenza season, peaking in the winter months. There has been 1 gastrointestinal illness outbreak investigated by DOH-Seminole in October.

Food and Waterborne Illness Complaints can be submitted at the following link. A health department employee will follow-up with the complainant by phone: <u>http://www.floridahealth.gov/diseases-and-conditions/food-and-waterborne-disease/online-food-complaint-form.html</u>



Ebola Virus Disease Update

<u>Current Statistics:</u>		Cases	Deaths	
	Guinea	3,805	2,536	
	Liberia*	10,672	4,808	
	Sierra Leone**	14,122	3,955	
	Total	28,599	11,299	

Case count as of November 8, 2015

The U.S., Nigeria, Senegal, Spain, Mali, and U.K. previously reported cases but have since been declared Ebolafree. * Liberia was declared Ebola-free on May 9, 2015. Following the declaration, 6 new cases were identified, including 2 deaths. On September 3, 2015, WHO again declared Liberia free of Ebola virus transmission. **On November 7, 2015, WHO declared Sierra Leone free of Ebola virus transmission after 42 days (two incubation periods) had passed since the last patient tested negative.

The Florida Department of Health continues to encourage healthcare providers and hospitals to prepare for an Ebola case in Florida.

The latest FDOH guidance on Ebola Virus Disease can be found at the following link:

http://www.floridahealth.gov/diseases-and-conditions/ebola/index.html

Disease Incidence Table-Seminole County

Selected Diseases/Conditions Reported to DOH-Seminole	2015 through Week 43	2014 through Week 43	2013 through Week 43	2012–2014 Average through Week 43
AIDS*	0	0	0	0.0
Animal Bite to Humans**	19	30	32	24.0
Animal Rabies	5	3	10	5.5
Campylobacteriosis	45	24	29	34.5
Chlamydia	1361	1181	1190	1239.5
Cryptosporidiosis	7	10	5	6.5
Cyclosporiasis	1	3	1	1.5
Dengue	1	2	2	2.0
E. coli Shiga toxin-producing	7	10	7	8.3
Giardiasis	13	14	8	13.0
Gonorrhea	309	232	257	273.5
Haemophilus influenzae (invasive)	0	2	9	3.0
Hepatitis A	0	2	0	1.3
Hepatitis B (acute and chronic)	72	54	41	55.8
Hepatitis C (acute and chronic)	394	297	246	310.3
Hepatitis B in Pregnant Women	5	1	4	3.8
HIV*	46	29	40	35.8
Lead poisoning	2	5	3	4.8
Legionellosis	9	5	9	6.3
Lyme Disease	1	4	4	2.8
Meningococcal Disease	1	1	1	1.0
Pertussis	12	18	8	12.3
Salmonellosis	82	85	67	79.0
Shigellosis	17	34	4	24.0
S. pneumoniae – drug resistant	3	5	11	6.3
Syphilis	92	68	46	61.8
Tuberculosis	2	5	4	4.5
Varicella	7	10	16	12.0

- * HIV data includes those cases that have converted to AIDS. These HIV cases cannot be added with AIDS cases to get combined totals since the categories are not mutually exclusive. AIDS data is current through March 2015.
- ** Animal bite to humans by a potentially rabid animal resulting in a county health department or state health office recommendation for post-exposure prophylaxis (PEP), or a bite by a non-human primate.

Reported cases of diseases/conditions in **Bold** are >10% higher than the previous three year average for the same time period.

All Data is Provisional





The Epidemiology Program conducts disease surveillance and investigates suspected occurrences of infectious diseases and conditions reported from physician's offices, hospitals and laboratories.

Surveillance is primarily conducted through passive reporting from the medical community as required by Chapter 381, Florida Statutes.

To report a reportable disease or outbreak during business hours please use the <u>Report of Communicable Disease Form</u>. Contact the Division of Epidemiology at 407-665-3266 for diseases other than HIV/AIDS and STDs.

To report an urgent reportable disease or outbreak after hours, call 407-665-3266 and follow the instructions to reach the on-call Epidemiologist.

Reportable Diseases/Conditions in Florida - Practitioner List Reportable Diseases/Conditions in Florida - Laboratory List Disease Reporting Information for Health Care Providers and Laboratories Foodborne Illnesses Reporting Links: Report illnesses due to food online 24/7 Report unsafe or unsanitary conditions Disaster Preparedness Link: http://www.floridadisaster.org/index.asp

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MISSION

To protect, promote and improve the health of all people in Florida through integrated state, county and community efforts

VISION To be the Healthiest State in the Nation

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