

Epidemiology Program • www.seminolecohealth.com

Investigational Drug Available Directly from CDC for the Treatment of Infections with Free-Living Amebae

In 2013 the Centers for Disease Control and Prevention (CDC) expanded access to an investigational new drug (IND) protocol in effect with the Food and Drug Administration (FDA) to make miltefosine available directly from CDC to clinicians for treatment of freeliving ameba (FLA) infections in the United States.

Infections caused by free-living amebae (FLA) are severe and life-threatening. These infections include <u>primary amebic meningoencephalitis (PAM)</u> caused by *Naegleria fowleri** and granulomatous amebic

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encephalitis caused by *Balamuthia mandrillaris* and *Acanthamoeba* species. Although several drugs have in vitro activity against FLA, mortality from these infections remains >90% despite treatment with combinations of drugs.

Miltefosine is a drug used to treat leishmaniasis and also has shown in vitro activity against FLA, but as an investigational drug, it has not been readily available in the United States. Through CDC assistance, however, miltefosine has been administered since 2009 for FLA infections as singlepatient emergency use with permission from the Food and

Drug Administration. Although the number of *B. mandrillaris* and *Acanthamoeba* species infections treated with a miltefosine-containing regimen is small, it appears that a miltefosine-containing treatment regimen does offer a survival advantage for patients with these often fatal infections.

CDC now has an expanded access investigational new drug (IND) protocol in effect with the Food and Drug Administration to make miltefosine available directly from CDC for treatment of FLA in the United States. The expanded access IND use of miltefosine for treatment of FLA is partly supported by 26 case reports of FLA infection in which miltefosine was part of the treatment regimen (Division of Foodborne, Waterborne, and Environmental Diseases, National Center for Emerging and Zoonotic Infectious Diseases, CDC, unpublished data, 2013). Miltefosine generally is well-tolerated, with gastrointestinal symptoms the most commonly reported adverse effects.

Clinicians who suspect they have a patient with FLA infection who could benefit from treatment with miltefosine should contact CDC to consult with an FLA expert. For diagnostic assistance, specimen collection guidance, specimen shipping instructions, and treatment recommendations, clinicians should contact the CDC Emergency Operations Center at 770-488-7100.

Amebic encephalitis is a reportable condition to the Florida Department of Health; if you suspect a case of amebic encephalitis please call (407) 665-3266.

Primary Amebic Meningoencephalitis Clinician Guide

The start of the warm weather season, the Florida Department of Health in Seminole County is a reminder for the healthcare community to remain vigilant in identifying cases of Primary Amebic Meningoencephalitis (PAM). PAM is caused by a free-living ameboflagellate, *Naegleria fowleri*, commonly found in the upper layer of sediment in the bottom of lakes and ponds with mud floors and is considered ubiquitous to Florida freshwater bodies. Florida has the second highest incidence of PAM in the U.S., after Texas.

PAM infection occurs when the ameba enters the brain and meninges through the nasal mucosa and olfactory nerve causing acute, fulminant hemorrhagic meningoencephalitis. The majority of infections with *Naegleria fowleri* occur following swimming or diving in freshwater lakes, rivers or hot springs, or thermally heated bodies of water. Infection may also occur when contaminated water from other sources (such as inadequately chlorinated swimming pool water or heated tap water <47°C) enters the nose, for example when people submerge their heads or cleanse during religious practices, and when people irrigate their sinuses.

The incubation period typically ranges from 1 to 7 days. Symptoms of an infection include headache, fever, nausea and vomiting and stiff neck accompanied by positive Kernig's and Brudzinski's signs. Other symptoms include photophobia, altered mental status, lethargy, dizziness, loss of balance and bodily control, other visual disturbances, seizures, hallucinations and coma. Almost all cases are fatal, usually within 5 to 6 days of onset. This infection cannot be spread from person to person or contracted from a properly maintained swimming pool.

Since initial symptoms of *N. fowleri* infection tend to be nonspecific and are often misdiagnosed, it is important for medical providers to inquire about the patient's water exposure history. PAM and *Naegleria fowleri* infection can be diagnosed in the laboratory by detecting:

- Naegleria fowleri organisms in cerebrospinal fluid (CSF), biopsy, or tissue specimens, or
- Naegleria fowleri nucleic acid in CSF, biopsy, or tissue specimens, or
- Naegleria fowleri antigen in CSF, biopsy, or tissue specimens.

Miltefosine, an investigational drug for the treatment of free-living ameba, is available upon request from the CDC. Miltefosine should be requested upon suspicion of PAM infection, laboratory confirmation is NOT needed to initiate treatment.

Additional information on PAM can be obtained from the CDC's website at http://www.cdc.gov/parasites/naegleria/.

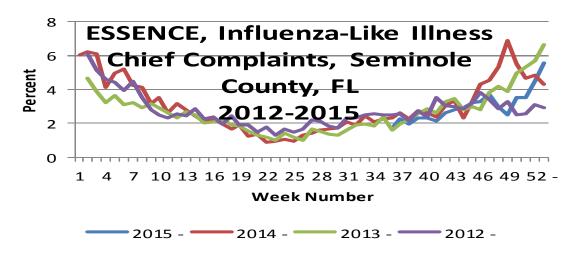
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Influenza Surveillance

Local: Seminole County has reported **MILD** flu activity since January. **Three(3) influenza outbreaks** have been reported in Seminole for the 2014-2015 Influenza season in nursing homes. The ESSENCE Syndromic Surveillance system is showing **DECREASING** influenza-like illness (ILI) chief complaints.

State: Florida is currently reporting **LOCAL** flu activity. Influenza activity has **DECREASED** since week 52. **One hundred and five (105) influenza or ILI outbreaks** have been reported this flu season. **Three (3) pediatric influenza-associated deaths** have been reported this season. The most common influenza subtype detected currently at the state laboratory is **Influenza B.**

National: Forty-nine (49) states are reporting **MINIMAL** flu activity. Since October 1, 2014 the CDC has identified an antigenically **drifted influenza A (H3N2) strain** circulating that is different from the influenza A (H3N2) strain contained in the current 2014-2015 influenza vaccine formulation. 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: N/A

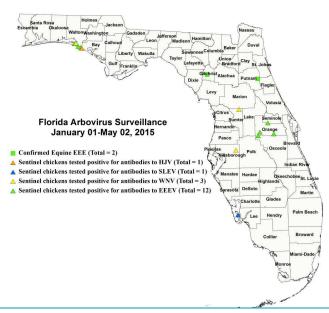
Eastern Equine Encephalitis: N/A

St. Louis Encephalitis: N/A

Dengue: One imported case

Chikungunya: One imported case

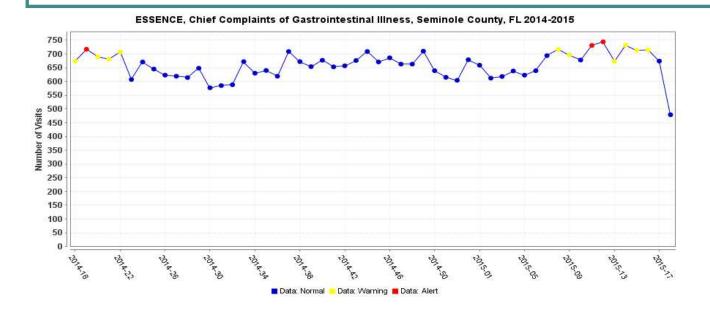
Malaria: N/A



Gastrointestinal Illness Surveillance

Gastrointestinal Illness typically follows a trend similar to influenza season, peaking in the winter months. No gastrointestinal outbreaks were reported in April.

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



Ebola Virus Disease Update

Current Statistics:

	Cases	Deaths
Guinea	3,597	2,392
*Liberia	10,604	4,769
Sierra Leone	12,523	3,904
Total	26,724	11,065

Case count as of May 10, 2015

The U.S., Nigeria, Senegal, Spain, Mali, and U.K. have all previously reported cases but have since been declared Ebola-free. * Liberia was declared Ebola-free on May 9, 2015.

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 16	2014 through Week 16	2013 through Week 16	2012–2014 Average through Week 16
AIDS*	9	7	12	8.7
Animal Bite to Humans**	5	7	7	5.7
Animal Rabies	3	0	3	1.7
Campylobacteriosis	22	10	9	12.3
Chlamydia	507	396	464	450.7
Cryptosporidiosis	5	1	1	1.3
Cyclosporiasis	0	0	0	0
Dengue	1	0	0	0
E. coli Shiga toxin-producing	2	3	2	3.7
Giardiasis	5	3	4	3.7
Gonorrhea	115	91	104	99.7
Haemophilus influenzae (invasive)	0	1	4	2.0
Hepatitis A	0	0	0	0.7
Hepatitis B (acute and chronic)	27	18	12	16.0
Hepatitis C (acute and chronic)	135	106	72	84
Hepatitis B in Pregnant Women	0	0	0	0
HIV*	14	13	11	9.7
Lead poisoning	1	1	0	2.7
Legionellosis	3	2	3	1.7
Lyme Disease	1	0	0	0.7
Meningococcal Disease	0	1	1	1.0
Pertussis	4	4	4	3.0
Salmonellosis	16	11	14	12.3
Shigellosis	7	1	1	6.7
S. pneumoniae – drug resistant	1	2	3	3.0
Syphilis	23	23	16	19.7
Tuberculosis	1	4	2	2.7
Varicella	5	5	10	8.3

^{• *} 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.

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

^{• **} 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.



Disease Reporting

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> for diseases other than HIV/AIDS, STD, or TB, or contact the Epidemiology Department at (407) 665-3266.

To report an urgent reportable disease or outbreak after hours, please contact (407) 665-3266 and follow the instructions to reach the Epidemiologist on-call 24/7.

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

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

VALUES

Innovation Collaboration Accountability Responsiveness Excellence

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