

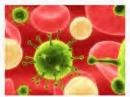
Epidemiology Program • www.seminolecohealth.com

CDC HEALTH ADVISORY: Fatal Gastrointestinal Mucormycosis in an Infant Following Ingestion of Contaminated Dietary Supplement

Mucormycosis is a rare infection caused by mold in the order Mucorales, including Rhizopus spp. GI mucormycosis is a very rare manifestation of this disease and occurs when mucormycosis involves the GI tract causing signs and symptoms such as:

- Abdominal pain
- Abdominal distension
- Nausea
- Vomiting

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These symptoms are thought to occur primarily when a susceptible person ingests the fungus, and they usually occur in immunocompromised individuals.

In October 2014, a hospital in Connecticut notified CDC and the Connecticut Department of Public Health of a fatal case of gastrointestinal mucormycosis in a preterm infant of 29 weeks' gestation. The infant received lot 074 024 01R1 of ABC Dophilus® Powder for four days, beginning on day one of life. ABC Dophilus® Powder is a product intended to contain three bacteria, Bifidobacterium lactis, Streptococcus thermophilus,

and Lactobacillus rhamnosus. The product was purchased from Solgar, Inc., Leonia, NJ, and is marketed specifically for infants and children. This product and other dietary supplements thought to have probiotic effects have been used in preterm infants on the basis of a recent Cochrane review supporting their use for prophylaxis against necrotizing enterocolitis (NEC), a possible complication in preterm infants. ABC Dophilus ® Powder is intended for use as a dietary supplement and, as such, is not regulated as a drug by the FDA. FDA has not evaluated the safety of this product for any intended use and has not evaluated the veracity of any claims of probiotic or other health benefits.

(Cochrane review link: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD005496.pub4/abstract;jsessionid=7664425A46560C7617A65EB3779F50C5.f02t02)

This infant subsequently developed clinical signs and symptoms of NEC. Surgical exploration of the infant's abdomen revealed complete GI ischemia from esophagus to rectum, a portion of necrotic bowel was resected. Following surgery, the infant developed multiple areas of vascular occlusion, a finding not associated with NEC. Shortly thereafter, the infant died.

Histopathologic results from the infant's necrotic bowel showed angioinvasive fungal infection, consistent with mucormycosis. immunohistochemical staining of the tissue block performed locally and at CDC was positive when tested with a monoclonal antibody known to react with several mucormycete fungal agents. Sequencing of fungal DNA recovered from the tissue block at CDC identified the fungus as

Rhizopus oryzae, a known cause of mucormycosis.

The hospital initiated an investigation into the infant's death, including evaluation of the Solgar ABC Dophilus® Powder product. Local testing of unopened bottles of lot 074 024 01R1 Solgar ABC Dophilus® Powder revealed contamination with mold, confirmed to be Rhizopus oryzae at CDC. On November 14, 2014, Solgar Inc. issued a voluntary recall (http:// www.fda.gov/Safety/Recalls/ucm423219.htm) of ABC Dophilus® Powder lots 074024-01R1, 074024-01, and 074024-02 (all with expiration dates of 7/31/15). This recall notice includes the instructions that "Consumers who have purchased Solgar ABC Dophilus® Powder are urged not to consume the product." This product was distributed to 29 states, Puerto Rico, the United Kingdom, and Israel through pharmacies, retail stores, wholesalers, and online retailers.

Investigation into this fatal case of GI mucormycosis following ingestion of contaminated Solgar ABC Dophilus® Powder is ongoing. National case finding efforts are underway to identify additional cases of GI mucormycosis following ingestion of this contaminated dietary supplement.

Recommendations

- Solgar ABC Dophilus® Powder should not be used, especially in infants who may be especially susceptible to infection.
- In considering the use of any dietary supplement, clinicians should consider that the FDA does not regulate these products as drugs.

Clinical Care

- Clinicians evaluating:
 - ♦ Preterm infants for necrotizing enterocolitis **OR**
 - Infants who have signs or symptoms of gastrointestinal mucormycosis such as abdominal pain, abdominal distension, nausea, or vomiting

Should review whether Solgar ABC Dophilus® Powder was used as part of the infants' care.

 If Solgar ABC Dophilus® Powder was consumed by the patient within the previous 30 days, clinicians should consider consultation with an infectious disease physician to assist in an assessment which may include the following:

- Aggressive evaluation for a source of infection, including surgical exploration.
- Empiric treatment with antifungals active against mucormycete infections.

Reporting

- Clinicians and public health officials are asked to notify their state or local health departments if they learn of cases or deaths in the following categories that have occurred since November 1, 2013:
 - Confirmed or suspected cases of infants with gastrointestinal mucormycosis (diagnosed via culture or histopathology).

OR

 Unexplained infant deaths within 30 days after ingesting Solgar ABC Dophilus® Powder.

For more information:

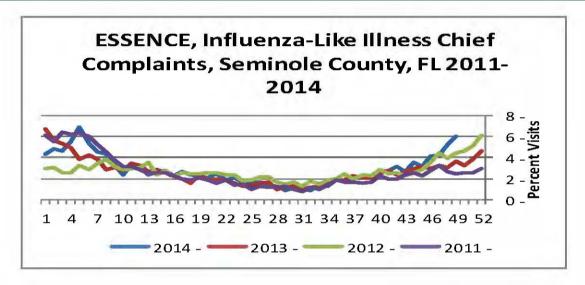
Please consult the CDC website for this investigation: http://www.cdc.gov/fungal/rhizopusinvestigation.html

Influenza Surveillance

Local: Seminole County is reporting MODERATE flu activity for the month of November. One influenza outbreak was reported in Seminole for the 2014-2015 Influenza season in a nursing home. The ESSENCE Syndromic Surveillance system is showing increasing influenza-like illness (ILI) chief complaints.

State: Florida is currently reporting REGIONAL flu activity. Thirteen influenza or ILI outbreaks have been reported this flu season. The first two pediatric influenza-associated deaths were reported in mid-November. The most common influenza subtype detected at the state laboratory is Influenza A (H3)

National: The CDC reports increasing influenza activity nationwide. 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 2014 Year to Date:

West Nile Virus: 19 positive Sentinel Chickens

Eastern Equine Encephalitis: N/A

St. Louis Encephalitis: N/A

Dengue: 2 Imported Cases

Chikungunya: 6 Imported Cases

Malaria: 1 Imported Case



Disease Incidence Table-Seminole County

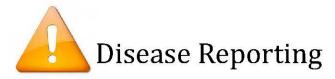
| Selected Diseases/Conditions Reported to DOH-Seminole | 2014 through Week 48 | 2013 through Week 48 | 2012 through Week 48 | 2011–2013 Average through Week 48 |
|--|-------------------------|-------------------------|-------------------------|--------------------------------------|
| AIDS* | 23 | 36 | 23 | 30.3 |
| Animal Bite to Humans** | 30 | 34 | 21 | 20 |
| Animal Rabies | 3 | 10 | 4 | 5.7 |
| Campylobacteriosis | 28 | 31 | 43 | 30.3 |
| Chlamydia | 1198 | 1227 | 1239 | 1245.7 |
| Cryptosporidiosis | 10 | 8 | 6 | 5.3 |
| Cyclosporiasis | 3 | 1. | 1 | 1.0 |
| Dengue | 2 | 2 | 3 | 0.7 |
| E. coli Shiga toxin-producing | 12 | 7 | 9 | 6.7 |
| Giardiasis | 14 | 9 | 18 | 11 |
| Gonorrhea | 257 | 258 | 291 | 257.7 |
| Haemophilus influenzae (invasive) | 3 | 10 | 1 | 3.3 |
| Hepatitis A | 3 | 0 | 3 | 1.6 |
| Hepatitis B (acute and chronic) | 62 | 44 | 63 | 49.7 |
| Hepatitis C (acute and chronic) | 419 | 282 | 334 | 234.3 |
| Hepatitis B in Pregnant Women | 1 | 4 | 5 | 5.3 |
| HIV* | 58 | 52 | 38 | 46.7 |
| Lead poisoning | 5 | 3 | 9 | 4.3 |
| Legionellosis | 5 | 10 | 6 | 3.3 |
| Lyme Disease | 4 | 4 | 3 | 2.7 |
| Meningococcal Disease | 1 | 1, | 1 | 0.7 |
| Pertussis | 18 | 8 | 11 | 7 |
| Salmonellosis | 101 | 77 | 95 | 60.3 |
| Shigellosis | 45 | 4 | 46 | 20 |
| S. pneumoniae – drug resistant | 4 | 12 | 6 | 8.7 |
| Syphilis | 25 | 16 | 16 | 19.0 |
| Tuberculosis | 5 | 4 | 4 | 5.3 |
| Varicella | 12 | 20 | 15 | 14 |

^{• *}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/HIV/STD/TB data are current through October 2014.

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.



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

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

ADDRESS

400 West Airport Boulevard Sanford, FL 32773



Contact Information

Health Officer Dr. Swannie Jett, DrPH, MSc
Environmental Health Manager Nancy Smith, BA, RS
Director of Community & Population Health Donna J. Walsh, RN, BSN, MPA
Epidemiology Program Manager Tania Slade, MPH

Epidemiology Peggy Booth, RN, BSN (407) 665-3294 (407) 665-3214 (fax) HIV/AIDS Willie Brown, BS (407) 665-3690 (407) 665-3265 (fax) **ADAP** Barbara Sevon, HSR (407) 665-3289 (407) 665-3265 (fax) STD/HIV/AIDS Preston Boyce, BS (407) 665-3698 (407) 665-3295 (fax) **Immunizations** Bertie Barber, RN, BSN (407) 665-3299 (407) 665-3255 (fax) **Tuberculosis** Patrice Boon, RN (407) 665-3298 (407) 665-3279 (fax)