Government of the District of Columbia
Department of Health

Division of Epidemiology-Disease Surveillance & Investigation

November 25, 2014

Fatal Gastrointestinal Mucormycosis in an Infant Following Ingestion of Contaminated Dietary Supplement – Connecticut, 2014

Summary

The Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and Connecticut Departments of Public Health and Consumer Protection are investigating a fatal case of gastrointestinal (GI) mucormycosis caused by* Rhizopus oryzae *in a premature infant. The infant received ABC Dophilus® Powder, a dietary supplement product containing viable microbial ingredients purchased from Solgar, Inc., Leonia, New Jersey. The product claimed to have "probiotic" properties and is marketed for infants and children. Subsequent testing of the same lot of unopened Solgar ABC Dophilus® Powder revealed contamination with* Rhizopus oryzae. *The purpose of this HAN advisory is to provide awareness about this fatal case of GI mucormycosis following ingestion of a contaminated dietary supplement and to provide guidance to state health departments and health care providers. Please disseminate this information to healthcare workers in neonatal intensive care units, hospital pharmacies, pediatricians, and primary care providers, as well as to microbiology and pathology laboratories.

Background

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

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.

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 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.

The District of Columbia requests that physicians report cases meeting the above case definition to the Department of Health (DOH). To report data, please use the Government of the District of Columbia Department of Health Communicable Disease Report Form and fax the form to DOH at (202) 442-8060. For additional information please call (202) 442-8141 during normal business hours.

For more information:
Please consult the CDC website

Sincerely,

John O. Davies-Cole, PhD, MPH
State Epidemiologist