This is an official CDC HEALTH ADVISORY

Distributed via the CDC Health Alert Network March 31, 2021, 4:00 PM ET CDCHAN-00441

Acute Non-Viral Hepatitis of Unknown Etiology Potentially Associated with an Alkaline Water Product

Summary

Five cases of acute non-viral hepatitis of unknown etiology in children were reported to the Southern Nevada Health District (SNHD) between November and December 2020. The Centers for Disease Control and Prevention (CDC) is assisting the SNHD in investigating a potential link between these illnesses and the consumption of an alkaline water product called "Real Water" and other possible etiologies. The purpose of this Health Alert Network (HAN) Advisory is to advise clinicians and health departments to have a high index of suspicion for cases of acute non-viral hepatitis and to report any cases to their local health authority.

Background

CDC and the U.S. Food and Drug Administration (FDA) were notified of five cases of acute non-viral hepatitis of unknown etiology in children by the SNHD in Nevada on March 13, 2021. The cases occurred in children ranging in ages from seven months to five years who presented to a hospital between November 10, 2020, and December 3, 2020, with signs and symptoms of vomiting, poor intake, and fatigue. Laboratory testing on the patients showed elevated hepatic transaminases, hyperbilirubinemia, coagulopathy, and a negative viral hepatitis serology panel. All patients required transfers to a pediatric tertiary-care specialty liver unit because of concerns for acute liver failure and the possible need for liver transplantations. All children recovered and were discharged home. In addition to these cases, several adults and other children living in the cases' households reported similar but mostly less severe symptoms including nausea, vomiting, anorexia, and fatigue.

Information to date from the preliminary epidemiologic investigation supports that there is a strong link between these cases of acute non-viral hepatitis and Real Water alkaline water. Real Water, Inc. owns this brand of alkaline water and has headquarters in Mesa, Arizona. This product is available in 5-gallon, 3-gallon, 1 gallon, 1.5 liters, 1 liter, and 500 ml bottles, and "Real Water" concentrate. Bottles and concentrate products are available for purchase online and in stores nationwide. Real Water has issued a recall on their products. The FDA advises consumers, restaurants, and retailers not to drink, cook with, sell, or serve Real Water alkaline water until more information is known about the cause of the illnesses. Further, FDA advises that Real Water not be given to pets.

Recommendations

For Clinicians

- 1) Counsel your patients (or their caregivers and guardians) to stop drinking, cooking with, or using Real Water until more is known about the cause of the illnesses per <u>FDA recommendations</u>.
- 2) Educate your patients on the signs and symptoms of acute hepatitis due to any cause, which may include fever, fatigue, loss of appetite, nausea, vomiting, abdominal pain, dark urine, light-colored stools, joint pain, and yellow skin or eyes; and the importance of seeking medical care.
- 3) Maintain a high index of suspicion for non-viral hepatitis in your differential diagnosis of acute hepatitis in adults and children presenting with compatible clinical findings.
- 4) Obtain a more detailed exposure history in patients when you suspect acute non-viral hepatitis. Possible etiologies associated with acute non-viral hepatitis include exposure to medications, contaminated water or food, dietary and herbal supplements, traditional or home remedies, wild-

- growing mushrooms and plants, and chemicals such as metals, solvents, paint thinners, or pesticides.
- Obtain early consultation with and/or referral to a gastroenterologist or infectious disease specialist for medical workup and management of patients with signs and symptoms of acute hepatitis.
- 6) Contact your local health authority to report cases of acute non-viral hepatitis of unknown etiology.
- 7) Contact your local poison center (1-800-222-1222) for information on chemical or drug-induced liver toxicity and report any cases.

For Public Health

- 1) Please contact CDC via email (NCEHOutbreak@cdc.gov) for case classification criteria, suggested reporting guidelines, case investigation forms, and other questions. Acute non-viral hepatitis is currently not a nationally notifiable disease. Case findings may be mainly from clinicians reporting who may recognize these illnesses in their patients. The forms provided by CDC will help prepare public health agencies to receive these reports from clinicians.
- 2) Consider conducting case-finding activities that leverage existing data sources such as hospital discharge data, electronic syndromic surveillance systems, your local poison center, and other applicable surveillance systems. Contact CDC at NCEHOutbreak@cdc.gov for guidance on search criteria.

For More Information

- FDA Investigation
- FDA Case Reporting:
 - MedWatch
 - Online
 - Paper
 - FDA Consumer Complaints
- Southern Nevada Health District FAQ
- American Association of Poison Control Centers

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Categories of Health Alert Network messages:

Health Alert Requires immediate action or attention, highest level of importance

Health Advisory May not require immediate action; provides important information for a specific incident or situation **Health Update** Unlikely to require immediate action; provides updated information regarding an incident or situation **HAN Info Service** Does not require immediate action; provides general public health information

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