

Montana Health Alert Network

DPHHS HAN

ADVISORY

Cover Sheet

DATE

April 2, 2021

SUBJECT

Acute Non-Viral Hepatitis of Unknown Etiology Potentially Associated with an Alkaline water product.

INSTRUCTIONS

DISTRIBUTE AT YOUR DISCRETION. Share this information with relevant SMEs or contacts (internal and external) as you see fit.



For LOCAL HEALTH DEPARTMENT reference only
DPHHS Subject Matter Resource for more information regarding this HAN, contact:

DPHHS CDCP

Epidemiology Section
1-406-444-0273

For technical issues related to the HAN message contact the Emergency Preparedness Section at 1-406-444-0919

DPHHS Health Alert Hotline:
1-800-701-5769

DPHHS HAN Website:
www.han.mt.gov

REMOVE THIS COVER SHEET BEFORE REDISTRIBUTING AND REPLACE IT WITH YOUR OWN

Please ensure that DPHHS is included on your HAN distribution list.
hshsan@mt.gov

Categories of Health Alert Messages:

Health Alert: conveys the highest level of importance; warrants immediate action or attention.

Health Advisory: provides important information for a specific incident or situation; may not require immediate action.

Health Update: provides updated information regarding an incident or situation; unlikely to require immediate action.

Information Service: passes along low level priority messages that do not fit other HAN categories and are for informational purposes only.

Please update your HAN contact information on the Montana Public Health Directory



DATE

April 5, 2021

SUBJECT

Acute Non-Viral Hepatitis of Unknown Etiology Potentially Associated with an Alkaline water product.

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 in Nevada. The cases 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. 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.

The preliminary epidemiologic investigation supports a strong link between these cases of acute non-viral hepatitis and consumption of Real Water alkaline water. 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.

INFORMATION

According to the FDA and the firm's recall notice, distribution of the product in Montana has been limited to online sales through Amazon.com and the firm's webpage. Although the product has been recalled it may still be available online through third party vendors.

RECOMMENDATIONS

For Clinicians

If non-viral hepatitis is suspected gather a more detailed exposure history. If patient reports consuming Real Water counsel them to stop drinking, cooking with, or using the product. Non-viral hepatitis is not normally a reportable illness, but at this time please report cases of acute non-viral hepatitis that may be related to this suspected outbreak to your local health department. See the CDC HAN for more detailed recommendations.

For Public Health

Please notify and coordinate with CDEpi if you identify a case of non-viral hepatitis that may be related to this suspected outbreak.

Please notify and coordinate with the Food and Consumer Safety Section if you are made aware of product still on the market or recently purchased online.

For More Information

FDA Investigation

<https://www.fda.gov/food/outbreaks-foodborne-illness/investigation-acute-non-viral-hepatitis-illnesses-real-water-brand-alkaline-water-march-2021>

FDA Case Reporting

MedWatch: <https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program>

- Online Volunteer Reporting: <https://www.accessdata.fda.gov/scripts/medwatch/>
- Paper: <https://www.fda.gov/media/85598/download>
- FDA Consumer Complaints: <https://www.fda.gov/safety/report-problem-fda/consumer-complaint-coordinators>

Southern Nevada Health District FAQ: <https://www.southernnevadahealthdistrict.org/faq-non-viral-hepatitis-linked-to-real-water-brand-alkaline-water/>

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 [FDA recommendations](#).
- 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.

- 5) 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](#)

The Centers for Disease Control and Prevention (CDC) protects people's health and safety by preventing and controlling diseases and injuries; enhances health decisions by providing credible information on critical health issues; and promotes healthy living through strong partnerships with local, national, and international organizations.

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

##This message was distributed to state and local health officers, state and local epidemiologists, state and local laboratory directors, public information officers, HAN coordinators, and clinician organizations##