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Health Advisory

Acute Hepatitis and Liver Failure Following the Use of a Dietary Supplement: PDPH Reporting Requirements

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On September 9, 2013, the Hawaii Department of Health (DOH) was notified of seven patients with severe acute hepatitis and sudden liver failure of unknown cause. The patients were previously healthy and sought medical care from May through September 2013. Clinicians reported that the seven patients had all used OxyELITE Pro, a dietary supplement marketed for weight loss and muscle gain, prior to illness onset.

The investigation is ongoing and the data presented are preliminary. To date, clinicians have reported 45 patients to the Hawaii DOH in response to a public health alert. Of those, 29 patients, including the original seven, were confirmed to have acute hepatitis after using a nutritional supplement for weight loss or muscle building. The date of the first reported laboratory test was used as a proxy for illness onset and ranged from May 10 through October 3, 2013. The most commonly reported symptoms included loss of appetite, light-colored stools, dark urine, and jaundice. Median laboratory values reported at the peak of illness were the following:

- aspartate aminotransferase (AST) 1,128 IU/L;
- alanine transaminase (ALT) 1,793 IU/L;
- alkaline phosphatase 150 IU/L; and
- total bilirubin 12.6 mg/dL.

Of the 29 identified patients, 24 (83%) reported using **OxyELITE Pro** during the 60 days prior to illness onset. There was no other dietary supplement or medication use reported in common by more than two patients.

National case finding efforts have identified several individuals from states outside Hawaii with reported OxyELITE Pro or other weight loss or muscle building dietary supplement use prior to the development of acute hepatitis of unknown cause. The Centers for Disease Control and Prevention (CDC), in collaboration with state and local health departments, is collecting additional clinical and epidemiologic information from these individuals to determine if this outbreak is national in scope.

Case Definition:

An individual with acute-onset hepatitis of unknown etiology that developed symptoms on or after April 1, 2013 following use of a non-prescription weight loss or muscle building dietary supplement during the 60 days prior to illness onset.

With acute-onset hepatitis of unknown etiology defined as having BOTH:

- ALT > 4 times the upper limit of normal
- Total bilirubin > 2 times the upper limit of normal

AND

- negative workup for infectious or other explicative etiologies for hepatitis. Workup for other potential etiologies should include:
  - Hepatic imaging (i.e., ultrasound/doppler, CT scan, MRI) not consistent with alternative, explicative etiologies
  - Negative viral hepatitis panel
  - No pre-existing diagnosis of chronic liver disease (e.g., autoimmune hepatitis, primary biliary cirrhosis, primary sclerosing cholangitis, Wilson's disease, hemochromatosis)
  - No recent hypotensive shock or septic episodes - No history of alcoholism documented in medical records

Evaluation and Reporting:

- Ask about consumption of dietary supplements when evaluating patients with acute hepatitis.
- Report patients meeting the case definition to **BOTH** of the following:
  - The Philadelphia Department of Public Health (PDPH) Hepatitis Epidemiology Program at ***215-685-6493***.
  - The US Food and Drug Administration's MedWatch program online at https://www.accessdata.fda.gov/scripts/medwatch/ or by phone at 1-888-INFO-FDA.