Indiana Health Alert Network Notification

Recall of MediChoice M500812 Ultrasound Gel

August 2021

The Centers for Disease Control and Prevention (CDC) is assisting the Food and Drug Administration (FDA) and several state and local health departments with an ongoing investigation of *Burkholderia cepacia* complex (Bcc) infections in healthcare facilities. Patients have developed Bcc infections, including bloodstream infections, after having undergone ultrasound-guided procedures in which **MediChoice® M500812 ultrasound gel** was used.

MediChoice M500812 ultrasound gel may have been used to guide ultrasonography in preparation for or during the procedures. Procedures have included ultrasound-guided placement of central and peripheral intravenous catheters and transcutaneous procedures including amniocentesis, paracentesis, and biliary drainage.

As of August 4, 2021, preliminary testing indicates the presence of *Burkholderia stabilis*, a member of Bcc, in 4 lots of unopened bottles of MediChoice® M500812 ultrasound gel (Lot # B031, B040, B048, B055). These *B. stabilis* product isolates genetically match *B. stabilis* isolates obtained from at least 15 patients across multiple states. Additional laboratory testing of isolates or specimens from patients with reported Bcc infections and of additional lots of MediChoice® M500812 ultrasound gel is currently underway.

As of August 4, 2021, the manufacturer of MediChoice®M500812 ultrasound gel (Eco-Med Pharmaceutical, Etobicoke, ON, Canada) has issued a recall of Eco-Gel 200® ultrasound gel (also labeled as MediChoice® M500812, among others) with lots: B029, B030, B031, B032, B040, B041, B048, B055. Per the manufacturer: "*Eco-Med is instructing all health care facilities to identify the affected products by lot number and immediately destroy or return products from affected lots to Eco-Med…Additionally, Eco-Med is instructing all health care facilities to immediately stop use and quarantine all lots of the following ultrasound gels distributed under these brand names.*" Please refer to https://eco-med.com/recall/ for additional information, including a list of the brand names.

CDC advises that healthcare facilities should always use single-use, sterile ultrasound gel packets for ultrasonography used in preparation for or during transcutaneous procedures, such as placement of central and peripheral intravenous lines, amniocentesis, and paracentesis. This includes avoiding use of bottles of nonsterile ultrasound gel for visualization prior to such procedures (e.g., vein marking, visualizing ascites). Healthcare facilities should also review facility practices related to ultrasound probe reprocessing to ensure they are aligned with manufacturer's instructions for use and appropriate professional society guidelines.

Healthcare facilities should report any patient infections occurring since March 26, 2021 related to the use of potentially contaminated medical products to FDA's MedWatch Adverse Event Reporting program at https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program.

Please send questions or concerns to IDOH Healthcare Associated Infections Epidemiologist Haley Beeman at hbeeman@isdh.in.gov or 317-234-2805.