From: CDC/DDID/NCHHSTP/DTE (CTR)
Date: Friday, June 11, 2021 at 7:37 AM
Subject: Multistate Tuberculosis Outbreak Linked to Suspected Contaminated Bone Graft Material Used in Surgery

Sending on behalf of Dr. LoBue

Dear Colleague,

On May 25, 2021, CDC received notification of a cluster of patients at a single facility who developed *Mycobacterium tuberculosis* (MTB) surgical site infection following spinal fusion surgery. As of June 10, 2021, post-operative patients from multiple facilities in multiple states have developed surgical site infections (abscess, phlegmon, osteomyelitis, and/or discitis) or other manifestations of MTB infection (e.g., miliary, disseminated, meningitis). MTB was isolated from the wounds of multiple patients during post-operative evaluations.

The surgical procedures all used **a single product lot of FiberCel, a bone allograft, manufactured by Aziyo Biologics and distributed by Medtronic (FiberCel lot NMDS210011)**. On June 2, the manufacturer issued a voluntary nationwide recall (attached) of the single lot of FiberCel linked to these patients.

The manufacturer reported that 154 units of this product, from a single donor, were shipped to more than 30 facilities in 20 states. CDC has worked with the affected state and local health departments to determine the disposition status of all distributed units of this lot and, where relevant, recipient patient clinical status. **All facilities and states have been contacted and all unused products have been sequestered. If you have not been contacted, then there were no affected lots delivered to your jurisdiction.**

There is **only one lot** that has been implicated in this investigation. The MTB isolate that was grown from affected patients was found to be susceptible to all first-line drugs (i.e., Rifampicin, Isoniazid, Pyrazinamide, Ethambutol (RIPE)). The genotype appears to be unique, but more information on genotyping and Whole Genome Sequencing will be shared as available. **CDC recommends that all patients who received this product lot immediately begin full treatment for TB disease.** Treatment recommendations for patients who received this product are attached to this email.

CDC encourages hospitals and providers to contact patients to notify them that the allograft material was contaminated and initiate full evaluation. Patients should be clinically evaluated as soon as possible both for post-operative infection as well as TB disease that may or may not have disseminated. Patients will need continued care from both surgical providers and TB providers to complete TB treatment.

Healthcare personnel may have been exposed to MTB via exposure to contaminated bone graft material during surgery or surgical revision or when providing patient care. It is important to rapidly identify and assess all exposed healthcare contacts for TB infection and disease. Healthcare personnel isolation precautions and a risk assessment for healthcare personnel and patient exposure to tuberculosis are attached to this email.

Facilities should report adverse health consequences to FDA's MedWatch Adverse Event Reporting Program:

- Online: www.fda.gov/MedWatch/report.htm
- Regular Mail: use postage-paid FDA form 3500 available at: www.fda.gov/MedWatch/getforms.htm and mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787
- Phone: (800) FDA-1088

If you have any questions, please reach out to your CDC project officer (list attached) or Sapna Bamrah Morris MD, FIDSA; Lead, Medical Officer Team; Field Services Branch Division of Tuberculosis Elimination; Centers for Disease Control and Prevention (sbmorris@cdc.gov).

Additional resources:

- Request medical consultation through the TB Centers of Excellence for Training, Education, and Medical Consultation
- Contact State TB Control Programs
- Contact CDC-INFO (cdcinfo@cdc.gov) for all other inquiries.

I would like to thank the affected state and local TB programs for their continued assistance.

Sincerely,

Philip LoBue, MD, FACP, FCCP
Director
Division of Tuberculosis Elimination
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

List of Attachments:

- *Aziyo Biologics, Inc. Recall Notice*
- *CDC initial diagnostic evaluation and treatment recommendations for patients who underwent spinal fusions or fracture repairs using FiberCel products from Lot NMDS210011 (version June 9, 2021)*
- *Healthcare personnel isolation precautions for tuberculosis (version June 7, 2021)*
- *Risk assessment for healthcare personnel and patient exposure to tuberculosis (version June 8, 2021)*
- *List of CDC Project Officers by Jurisdiction*