



**CABINET FOR HEALTH AND FAMILY SERVICES
DEPARTMENT FOR PUBLIC HEALTH**

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Dear Healthcare Provider:

[Note: This is a statewide health alert that updates a previous alert sent on December 18, 2018.]

The Kentucky Department for Public Health (KDPH) is updating you about a cluster of adverse vaccination reactions, including multiple local site infections with a mycobacterium species. There is no evidence to suggest that this is a vaccine safety or syringe manufacturer issue, as reactions continue to be limited to one vaccination provider. New infections are still being identified and can be difficult to treat, so we want to highlight the need for continued vigilance and appropriate evaluation, treatment, and revaccination.

Abscesses at the site of injection and inflammatory or fibrous nodules have been reported following the administration of hepatitis A, Tdap, pneumococcal, or seasonal influenza vaccinations. If you encounter this in your practice, we highly recommend a workup for nontuberculous mycobacteria (NTM), along with other bacterial and fungal pathogens. The following cultures and stains are recommended and should be obtained from the lesions, abscesses, or surgical specimens:

- Anaerobic culture
- Aerobic culture
- Fungal culture
- AFB smear and culture

Clinicians have also reported removing “nodules” or “knots” from the sites of infection where injections were previously administered. Any biologic material from tissue debridement or surgical excision should be sent for the same cultures listed above and should also be sent to pathology for analysis.

Antibiotic susceptibility testing on recovered organisms should be obtained in order to inform antibiotic therapy. A mycobacterium species has been identified from cultures from numerous patients.

Given that these organisms are not commonly encountered in primary care practice, it is recommended that affected patients be referred to an infectious disease specialist for consultation and potential ongoing management.

Given the identification of substantial issues with improper vaccine storage and handling, we have serious concerns that the vaccines administered by this provider may not have afforded protection to vaccine recipients. Consequently, revaccination is recommended as the prudent course of action.

Reactions (abscesses, fibroid knots) are associated with a single vaccination provider in a rural county who was providing vaccination clinics at Kentucky, Indiana, and Ohio businesses. Investigation is ongoing. The provider has ceased vaccinating and there is no continuing risk to the public. However, reactions have been identified more than 12 weeks after vaccination and patients may continue to present beyond this timeframe. We have no evidence to suggest manufacturer (pre-provider) contamination of the needles or syringes. Consequently, we do not recommend specific testing for bloodborne pathogens such as HIV or hepatitis B.

Specimens can be submitted through your regular laboratory network or directly to the Kentucky State Division of Laboratory Services (DLS) for those with access to the Outreach system. For more information, visit the Kentucky DLS website: <https://chfs.ky.gov/agencies/dph/dls/Pages/default.aspx>, or call Rachel Zinner or Rhonda Lucas at 502-564-4446. Laboratories should not discard specimens until KDPH has received reports and advised providers and laboratories about next steps.

KDPH requests information on any patient with an adverse vaccination reaction with onset on or after September 1, 2018. Any adverse vaccination reaction should be reported on the Department of Health and Human Services' Vaccine Adverse Event Reporting System (VAERS) at: <https://vaers.hhs.gov/>. *For the current situation, all vaccine reactions, positive lab results, or diagnoses consistent with the information above, should also be reported to the Kentucky Department for Public Health via phone or secure fax.*

Phone number: 1-888-9-REPORT

Secure fax: 502-696-3803

With flu season and the ongoing hepatitis A outbreak, we urge you to continue to vaccinate at-risk populations.

Thank you for your assistance in this matter!

Respectfully,

Mel Bennett, MD, MPH
Director, Infectious Disease Branch