

Notes from the Field

Adverse Reaction After Vaccinia Virus Vaccination — New Mexico, 2016

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On February 4, 2016, the New Mexico Department of Health (NMDOH) was contacted regarding a patient who had received ACAM2000* smallpox (vaccinia) vaccine 12 days earlier as part of an institutional review board–approved study at a plasma donation center and had numerous lesions surrounding the inoculation site and on the opposite arm, back, and abdomen. ACAM2000 is a live-virus vaccine indicated for active immunization against smallpox. Vaccinia virus is highly effective in preventing smallpox by stimulating an immune response to the closely related *Orthopoxvirus*. The inoculation site is considered infectious until the scab falls off and intact skin has regrown (2–4 weeks) (1,2). The patient, a man aged 57 years, had no ocular, oral, nasal, or genital lesions. He enrolled in the study on January 22, after meeting inclusion criteria and not having a condition that precluded vaccination (immunosuppression, heart disease, or history or presence of eczema) (1). The vaccination study objective was to induce production of high antivaccinia virus antibody titers for the collection of plasma to be used in manufacturing vaccinia immune globulin intravenous (VIGIV), which is produced by removing and purifying antivaccinia antibodies from plasma of persons with immunity to smallpox.

Adverse reactions to vaccinia vaccination range from mild and self-limited to severe and life-threatening, including inoculation site signs and symptoms, constitutional symptoms, generalized vaccinia, eczema vaccinatum, and progressive vaccinia (1,3). The most frequent complication is inadvertent inoculation at other sites (self and contacts) (2–4) with an estimated occurrence rate of 42.1 cases per 1 million vaccinations (1). Autoinoculation, the unintentional transfer of virus from the vaccination site to elsewhere on the vaccinee's body, can occur from hands or fomites; the most common nonocular transfer sites are the arm, elbow, and shoulder (2,3). Autoinoculation lesions progress through the same stages as the vaccination site lesion; when autoinoculation occurs >5 days postvaccination, lesions and progression are often attenuated (2,3).

Study participants received instructions regarding proper inoculation site management and hand hygiene and materials for wound care. On February 3, (day 11 postvaccination), the patient reported a fever of 101°F (38°C) and three lesions near

the inoculation site. On February 4, he arrived at the plasma center with numerous lesions surrounding the inoculation site and 20–30 lesions on his contralateral arm, abdomen, and back. Plasma center personnel requested NMDOH assistance in arranging possible hospital admission for VIGIV treatment.

After consulting CDC's Poxvirus and Rabies Branch, NMDOH interviewed the patient and plasma center personnel, communicated with the local hospital and its infectious disease consultant, assessed the patient's residence, and collected specimens from the inoculation site and surrounding lesions. The patient lived alone in a communal apartment building with shared bathrooms, kitchen, laundry facility, and fitness center. He showered in an older unit with limited use by other residents and did not share linens or towels, cook, or use the gym. He had a private bedroom, did not share his bed, and did not report any visits by friends or family members to his single-room apartment. He reported cleaning around the inoculation site with alcohol wipes when changing the dressing. On the basis of the patient interview and review of photos of the transferred lesions, neither hospitalization nor treatment with VIGIV was recommended. The plasma donation center reported the event to the Vaccine Adverse Events Reporting System (VAERS).[†]

DNA for both *Orthopoxvirus* and nonvariola *Orthopoxvirus* was detected from the patient's specimens, consistent with ACAM2000 vaccination. The patient's lesions likely resulted from inadvertent autoinoculation caused by handling the area around the vaccination site during redressing. To prevent additional direct or indirect transmission, NMDOH advised the patient regarding proper vaccination site bandaging and hand hygiene, cleaning communal spaces (e.g., shower and sinks) with bleach, doing his own laundry, and refraining from gym use until all lesions resolved.

Although inadvertent inoculation is a recognized adverse event following vaccination with vaccinia virus, neither NMDOH nor four of five other public health departments were aware that this study was being conducted, demonstrating the need for communication among commercial sites and state and local health departments to ensure establishment of mutually acceptable patient care protocols. Coordination among the patient, plasma center personnel, hospital, infectious disease consultants, and NMDOH helped prevent spread to others. Adverse events occurring after receipt of vaccines should be reported to VAERS.

[†] <https://vaers.hhs.gov/index>.

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References

1. Food and Drug Administration. Highlights of prescribing information. ACAM2000 (smallpox [vaccinia] vaccine, live). Silver Spring, MD: US Department of Health and Human Services, Food and Drug Administration; 2015. <http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142572.pdf>
2. Tack DM, Karem KL, Montgomery JR, et al. Unintentional transfer of vaccinia virus associated with smallpox vaccines: ACAM2000 compared with Dryvax. *Hum Vaccin Immunother* 2013;9:1489–96. <http://dx.doi.org/10.4161/hv.24319>
3. Casey C, Vellozzi C, Mootrey GT, et al. Surveillance guidelines for smallpox vaccine (vaccinia) adverse reactions. *MMWR Recomm Rep* 2006;55(No. RR-1).
4. Wenger P, Oleske JM, Kohl KS, et al. Inadvertent inoculation as an adverse event following exposure to vaccinia virus: case definition and guidelines for data collection, analysis, and presentation of immunization safety data. *Vaccine* 2007;25:5754–62. <http://dx.doi.org/10.1016/j.vaccine.2007.02.087>