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Smallpox Vaccine Administration

Meeting OSHA's Safety Requirements

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THOSE WHO ADMINISTER THE SMALLPOX vaccine have a two-fold risk: exposure to the patient's blood and body fluids, and exposure to vaccinia, the virus used for smallpox vaccination, through accidental inoculation from a needlestick. Earlier this year, OSHA published a document on its website that addressed questions related to smallpox vaccination and healthcare worker safety ("Frequently Asked Questions: OSHA's Bloodborne Pathogens Standard and Smallpox Vaccination Programs"). You can find the FAQ at: www.osha.gov/SLTC/bloodbornepathogens/bloodborne_faq.html.

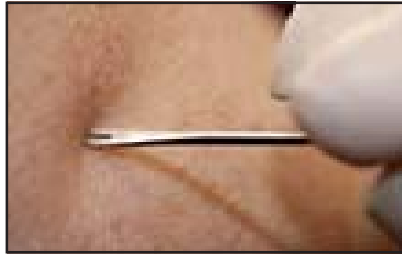
Developed in cooperation with the Centers for Disease Control and Prevention, the FAQ discusses what the bloodborne pathogens standard (BPS) requires in order to reduce exposure risks for healthcare workers administering the vaccine. Although fewer healthcare workers and emergency responders have chosen to receive smallpox vaccination than was initially expected and recommended by the federal government, the program is ongoing. (As of 9/26/03, 38,489 individuals have been vaccinated in the U.S. under the current program.) Thus the safety of workers administering the vaccine remains a concern.

Here is what healthcare employers and those in charge of smallpox vaccination programs need to do to meet OSHA's requirements:

- Update your facility's exposure control plan to address smallpox vaccination; include job classifications that administer the vaccina-

tions, provide follow-up care, or handle vaccination-related waste.

- Provide specific training for all employees who administer the smallpox vaccine ("vaccinators"), even if they've previously been trained in giving other kinds of vaccinations. Use instructions from the



vaccine manufacturer and training materials developed by the CDC for this purpose (www.bt.cdc.gov/agent/smallpox/training/index.asp).

- During training, discuss exposure risks associated with giving the vaccine, and how to safely use and dispose of the special "bifurcated" (two-pronged) needle used for smallpox vaccination (see photo above). The two prongs are used to pierce the skin's surface, and the space between them holds a precise dose of the vaccine. The needle will be unfamiliar to most healthcare workers since it is unique to smallpox vaccination.

- Instruct vaccinators to check that their vaccination supplies, including sharps container, are close at hand before beginning the procedure. Vaccinators should carefully explain to vaccinees in advance what they are going to do during

the procedure, and warn vaccinees that inadvertent movement on their part could cause a sharps injury to the vaccinator.

- Vaccinators should be trained to maintain visual contact with the needle until vaccination is complete and the needle is placed in the disposal container. The needle should be disposed of immediately after use. (If bifurcated needles must be reprocessed, safety measures should be in place to prevent injury after use and during reprocessing.)
- Employees should be instructed to pick up bifurcated needles that have been dropped with forceps if possible, in order to minimize risk of a sharps injury. Workers should never touch the sharp end of the needle.
- Vaccine vials and blood-contaminated gauze should be disposed of in the appropriate waste containers, in accordance with applicable state, county, and municipal regulations.

What are the risks to healthcare workers from smallpox vaccine administration?

Giving the smallpox vaccine requires the vaccinator to hold the vaccinee's upper arm and puncture the skin rapidly with the bifurcated needle, two or three times for first-time or "primary" vaccinees (and an additional three times if blood doesn't appear), and 15 times for those being revaccinated. When performing this procedure, the thumb is in fairly close proximity to the

needle (see photos below). If the needle slips or the vaccinee inadvertently moves while the vaccinator is puncturing the skin, a needlestick could occur.

If the vaccinator is stuck with the needle, the primary risk is likely to be from exposure to the vaccinee's blood and body fluids and possible transmission of a bloodborne pathogen. A secondary risk is accidental inoculation with the vaccinia virus. The CDC recommends that those who administer the vaccine be first vaccinated themselves, and also recommends that those for whom smallpox vaccination is contraindicated (e.g., those with eczema or other skin conditions, weakened immune systems, heart conditions, etc.) *not* administer the vaccine. However, the possibility of the vaccinator—or other clinic or hospital workers, such as housekeepers, who handle post-vaccination waste—being accidentally inoculated still exists. Most people have only mild reactions to the smallpox vaccine, such as a sore arm, fever, or body aches. But others may have reactions ranging from “serious to life-threatening,” according to the CDC, including “a toxic or allergic reaction at the site of the vaccination (erythema multiforme), spread of the vaccinia virus to other parts of the body and to other individuals (inadvertent inoculation), and spread of the vaccinia virus to other parts of the body through the blood (generalized vaccinia).” These types of reactions may require medical attention. If healthcare workers are stuck and accidentally inoculated, they run the same risk of side effects (from mild to serious to life-threatening) as the vaccinee.

Are safety devices required for smallpox vaccine administration?

The BPS requires employers to evaluate and implement safety-engineered sharp devices as a primary method of eliminating or minimizing

employees' exposure to blood and other potentially infectious materials. At least one safety-engineered bifurcated needle, made by Univec, is currently on the market. Another, BD's Eclipse Bifurcated Needle, will be available in December, according to a BD representative.

However, in March 2003 the CDC stated the following: “The Food



and Drug Administration has approved a new 100-dose kit for the administration of Dryvax smallpox vaccine with Precision bifurcated needles. Only Precision bifurcated needles were included in the approved kit. Any change in the kit would require FDA review. The needle accompanying the vaccine in the vaccine kits is the only needle that has been licensed for use with this vaccine.”

What does OSHA say? According to Amber Hogan, senior industrial hygienist with OSHA's Office of Health Enforcement, “OSHA enforcement is done on a facility-by-facility basis, so we do require the evaluation and selection (if appropriate and available) of safer bifurcated needles. If a facility determines that their use is neither appropriate nor effective, it can continue to use a conventional bifur-

cated needle, but it must document this choice in the exposure control plan and evaluate any new devices that become available in the future.” Since new safety devices for smallpox vaccine administration are being introduced to the market, facilities should keep abreast of the latest technology.

What should I do if I sustain a percutaneous injury while administering the smallpox vaccine?

According to OSHA, “an employer's obligations if an employee sustains a needlestick injury during smallpox vaccine administration would be the same as for any other needlestick injury.” The CDC has established a voluntary system for reporting smallpox vaccination-related needlesticks/blood exposures/exposures to vaccinia virus. A report form (Smallpox Vaccination Clinic Blood and Body Fluid Exposure Report) and other information are available at: www.bt.cdc.gov/agent/smallpox/vaccination/administration.asp.

The CDC recommends the following when a smallpox vaccinator sustains an exposure:

- Report the incident as you would any other sharps injury or blood exposure.
- Manage the exposure according to current CDC recommendations for immediate and follow-up treatment of occupational blood exposures.
- Complete an exposure report, and record the incident in the facility's sharps injury log.
- Conduct a “root cause” analysis to identify factors contributing to the exposure and preventive measures that should be implemented. (Both the exposed employee and the supervisor should have input into this analysis.)
- Within 48 hours of the exposure event, fax a copy of the completed exposure report and root cause analysis to the CDC at (404) 498-1244. □