

**WEBCAST TRANSCRIPT****Transcript of "Smallpox Vaccine Contraindications and Screening"**

Presented by Dr. William Atkinson, 6 December 2002, on the satellite broadcast of "CDC Bioterrorism Update: Smallpox Preparedness"

(Associated graphics can be found at www.bt.cdc.gov/agent/smallpox/training/webcast/dec2002/files/contra-and-screening.ppt and www.bt.cdc.gov/agent/smallpox/training/webcast/dec2002/files/contra-and-screening.pdf.)

(Slides 1 and 2 are title and objectives, respectively)

ATKINSON:

In this segment I would like to expand on a few of the issues discussed on the tape, primarily screening for contraindications to smallpox vaccination. Careful screening for contraindications is the best way to reduce the risk of adverse reactions, and **MUST** be done for **EVERY** person prior to vaccination.

Slide 3

Let's review briefly the contraindications and precautions to smallpox vaccination. In non-emergency situations, smallpox vaccine should not be administered to persons known to have a serious allergy to a prior dose of vaccine or vaccine component; persons with significant immunosuppression from any cause or someone with an immunosuppressed household contact; a woman who is pregnant or attempting to become pregnant, or someone with a household contact who is pregnant; and women who are breastfeeding.

Slide 4

Smallpox vaccine should not be administered to persons with a diagnosis of eczema or atopic dermatitis, including eczema or atopic dermatitis that is not currently active; or a person who has a household contact who has eczema or atopic dermatitis or a history of these diseases; persons with other extensive exfoliative skin conditions or a person who has a household contact with one of these conditions; children less than 12 months of age; and persons with a moderate or severe acute illness.

Slide 5

As you heard in earlier presentations, state health departments will identify volunteers willing to serve on public health smallpox response teams. States will also identify hospitals willing to assemble healthcare smallpox response teams. After volunteers are identified, they should be given information about the vaccine, and some time to consider whether or not they wish to receive the vaccine. We refer to this as "pre-screening". The idea behind this pre-screening period is to allow volunteers to withdraw without revealing any personal medical information.

Slide 6

A large packet of written materials will be provided to each volunteer. This packet contains a variety of material about smallpox vaccine, contraindications, and adverse events.

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Slide 7

A lengthy advice letter will be provided that outlines the risks and benefits of the vaccine; things to consider if the volunteer, or someone in their family, has possible contraindications, and possible risks involved with their employment should an adverse reaction occur. Other written materials will include a Vaccine Information Statement on smallpox vaccine and detailed information statements about contraindications; including immune system problems, skin conditions and pregnancy. Finally, volunteers will be given a checklist asking them to screen themselves for possible contraindications. They will not return this form, but can use it as an aid to help them decide whether or not they should be vaccinated.

Slide 8

Immunosuppressed persons, including people with HIV infection or AIDS are at increased risk of progressive vaccinia following smallpox vaccination. So smallpox vaccine should not be administered to persons with HIV infection or AIDS, or any other immunosuppressive condition. Before vaccination, potential vaccinees should be educated about the risk of severe complications among persons with HIV infection or other immunosuppressive conditions. Persons who think they may have one of these conditions should not be vaccinated.

Slide 9

The Advisory Committee on Immunization Practices (ACIP) does NOT recommend mandatory HIV testing prior to smallpox vaccination. But HIV testing IS recommended for people who have a history of a risk factor for HIV infection and who are not sure of their HIV infection status. Because risk factors cannot be identified for some people with HIV infection, testing should be readily available for anyone who is concerned that they could have HIV infection and wishes to be tested. HIV testing should be available in a confidential or, where permitted by law, anonymous setting with results communicated to the potential vaccinee before the planned date of vaccination. Persons with a positive test result should be told not to present to the vaccination clinic for immunization. Information about local testing options should be provided to all potential vaccinees, including sites where testing is performed at no cost.

Slide 10

Fetal vaccinia is a rare, but serious, complication of smallpox vaccination during pregnancy or shortly before conception. So smallpox vaccine should not be administered in a pre-event setting to pregnant women or to women who are trying to become pregnant. Before vaccination, women of child-bearing age should be asked if they are pregnant or intend to become pregnant in the next 4 weeks. Women who respond positively should not be vaccinated. In addition, the potential risk to the fetus should be explained. Women who are vaccinated should be advised to avoid becoming pregnant during the 4 weeks after vaccination. Routine pregnancy testing of women of child-bearing age is not recommended.

Slide 11

A woman who thinks she could be pregnant or who wants additional assurance that she is not pregnant should perform a home pregnancy test with a "first morning" void urine on the day scheduled for vaccination. If a pregnant woman is inadvertently vaccinated or if she becomes pregnant within 4 weeks after smallpox vaccination, she should be counseled regarding the basis of concern for the fetus. However, vaccination during pregnancy should not ordinarily be a reason to terminate the pregnancy. To expand our understanding of the risk of fetal vaccinia, a pregnancy registry should be maintained and any adverse outcomes carefully investigated.

Slide 12

Screening for skin conditions in potential vaccinees can be difficult. Eczema and atopic dermatitis is a risk factor for developing eczema vaccinatum following smallpox vaccination in either vaccinees or in their close contacts. This increased risk is independent of the activity of the skin condition. Due to this increased risk, smallpox vaccine should not be administered to persons with a history of eczema or atopic

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dermatitis, irrespective of disease severity or activity. In addition, persons with household contacts with a history of eczema or atopic dermatitis, irrespective of disease severity or activity, should not be vaccinated. Persons with other acute, chronic, or exfoliative conditions, such as burns, impetigo, varicella zoster, herpes, severe acne, or psoriasis, are at higher risk for inadvertent inoculation and should not be vaccinated until the condition is under good control or resolves.

Slide 13

The majority of providers do not routinely make the distinction between eczema and atopic dermatitis, particularly when describing chronic exfoliative skin conditions in infants and young children. To assist providers in identifying persons that should defer smallpox vaccination, ACIP offers the following two screening questions: 1) Have you, or a member of your household ever been diagnosed with eczema or atopic dermatitis. If the person answers "yes," he or she should NOT receive the smallpox. 2) Eczema and atopic dermatitis usually is an itchy red, scaly rash that lasts more than 2 weeks and often comes and goes. If the person or a member of their household has ever had a rash like this they should be vaccinated unless the person and a healthcare provider are certain that this rash is not atopic dermatitis or eczema.

My final issue has to do with smallpox vaccination and blood donation. Like other live virus vaccines, there will be a deferral period for blood donation following receipt of smallpox vaccine. For this reason, we encourage individuals to donate PRIOR to being vaccinated. In the near future, the FDA will release guidance that will include specific recommendations for the deferral period for donors who receive smallpox vaccine.

END

For more information, visit www.cdc.gov/smallpox, or call the CDC public response hotline at (888) 246-2675 (English), (888) 246-2857 (Español), or (866) 874-2646 (TTY)

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