

**SMALLPOX FACT SHEET – *Information for Clinicians*****Smallpox (Vaccinia) Vaccine Contraindications**

Because the vaccinia virus used in smallpox vaccine can be spread to others from the vaccine site of an immunized person, the contraindications below apply to **both potential vaccinees and their household contacts** ("household contacts" include persons with prolonged intimate contact with the potential vaccinee, including the potential for direct contact with the vaccination site, e.g., sexual contacts).

**Eczema or atopic dermatitis and other acute, chronic, or exfoliative skin conditions**

- Persons who have ever been diagnosed with eczema or atopic dermatitis should not be vaccinated, even if the condition is not currently active. These patients are at high risk of developing eczema vaccinatum, a potentially severe and sometimes fatal complication. Additionally, persons with household contacts that have a history of eczema or atopic dermatitis, irrespective of disease severity or activity, should not be vaccinated.
- If the potential vaccinee or any of their household contacts have other acute, chronic, or exfoliative skin conditions (e.g., burns, impetigo, chicken pox, contact dermatitis, shingles, herpes, severe acne, severe diaper dermatitis with extensive areas of denuded skin, or psoriasis), they are at risk for inadvertent autoinoculation of the affected skin with vaccinia virus and should not be vaccinated until the condition(s) resolves.
- Persons with Darier's disease can develop eczema vaccinatum and therefore should not be vaccinated.

**Diseases or conditions which cause immunodeficiency or immunosuppression**

- If a potential vaccinee or any of their household contacts have conditions such as HIV/AIDS, solid organ or stem cell transplant, generalized malignancy, leukemia, lymphoma, or agammaglobulinemia, they should not be vaccinated. People with these conditions are at greater risk of developing a serious adverse reaction resulting from unchecked replication of the vaccine virus (progressive vaccinia). It is also reported that some patients with severe clinical manifestations of some autoimmune diseases (e.g., systemic lupus erythematosus) may have some degree of immunocompromise as a component of the disease. These patients should not receive smallpox vaccine during the pre-event vaccination program.
- HIV testing should be readily available to all persons considering smallpox vaccination. HIV testing is recommended for persons who have any history of a risk factor for HIV infection and who are not sure of their HIV infection status. Anyone who is concerned that they could have HIV infection also should 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.

**Treatments which cause immunodeficiency or immunosuppression**

- If a potential vaccinee or any of their household contacts are undergoing treatment with radiation, antimetabolites, alkylating agents, high-dose corticosteroids (i.e.,  $\geq 2$  mg/kg body weight or 20 mg/day of prednisone for  $\geq 2$  weeks), chemotherapy agents, or organ transplant medications, they should not be vaccinated. People who are receiving these therapies are at greater risk of serious adverse reactions to the smallpox vaccine.

- People undergoing treatment with high dose corticosteroids, or who have household contacts undergoing such treatment, should not be vaccinated within one month of completing corticosteroid therapy. Persons undergoing other treatments which cause immunosuppression or who have household contacts undergoing such treatment should not receive smallpox vaccine until they or their household contact have been off immunosuppressive treatment for 3 months.

## **Pregnancy**

- Live virus vaccines are generally contraindicated during pregnancy. Pregnant women who receive the smallpox vaccine are at risk of fetal vaccinia. Although this is a very rare condition (fewer than 50 cases have ever been reported), it usually results in stillbirth or death of the infant shortly after delivery.
- Before vaccination, people should be asked if they or any of their household contacts are pregnant or intend to become pregnant in the next 4 weeks; those who respond positively should not be vaccinated.  
In addition, women who are vaccinated should be counseled not to become pregnant during the 4 weeks after vaccination, and abstinence or highly effective contraceptive measures should be recommended to reduce the risk of pregnancy within four weeks of vaccination.
- Routine pregnancy testing of women of child-bearing age is not recommended.
- Any woman who thinks she could be pregnant or who wants additional assurance that she is not pregnant should perform a urine pregnancy test using a “first morning” void urine on the day scheduled for vaccination. However, women should be informed that a negative urine pregnancy test cannot exclude a very early pregnancy and therefore they and their healthcare providers should not base a decision about their pregnancy status solely upon a urine pregnancy test result.
- If a pregnant woman is inadvertently vaccinated or if she becomes pregnant within 4 weeks after vaccinia 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 pregnancy.

**The contraindications above apply to potential vaccinees and their household contacts. The following additional contraindications apply only to potential vaccinees:**

### **Previous allergic reaction to smallpox vaccine or any of the vaccine’s components**

- Vaccinia vaccine (Dryvax®) contains small amounts of polymyxin B sulfate, streptomycin sulfate, chlortetracycline hydrochloride, neomycin sulfate, and phenol. Anyone who has experienced an anaphylactic reaction to these components should not be vaccinated.
- In addition, anyone who has experienced a previous allergic reaction to the smallpox vaccine should not be vaccinated.

### **Moderate or severe acute illness**

- Moderate or severe acute illness is generally a contraindication to vaccination.
- Vaccination should be deferred until the acute illness has resolved.

### **Infants and children**

- Smallpox vaccine is contraindicated for children under 12 months of age.
- The Advisory Committee on Immunization Practices (ACIP) advises against non-emergency use of smallpox vaccine in persons younger than 18 years of age.

## **Breastfeeding**

- Breastfeeding mothers should not receive the smallpox vaccine. The close physical contact that occurs during breastfeeding increases the chance of inadvertent inoculation. It is not known whether vaccine virus or antibodies are excreted in human milk.

## **Heart disease, temporary deferral**

- CDC recommends that persons with known cardiac disease such as previous myocardial infarction, angina, congestive heart failure, or cardiomyopathy not be vaccinated at this time. This recommendation follows reports of cardiac events following smallpox vaccinations including myocardial infarctions and angina without myocardial infarction. It is unclear whether or not there is any association between smallpox vaccination and these cardiac events. Experts are exploring these issues more in depth. This exclusion may be removed as more information becomes available.

## **General precautions:**

- The vaccine vial stopper contains dry natural rubber that may cause hypersensitivity reactions when handled by, or when the product is administered to, persons with known or possible latex sensitivity.
- Persons with inflammatory eye diseases may be at increased risk for inadvertent inoculation due to touching or rubbing of the eye. Therefore it may be prudent to defer vaccination of persons with inflammatory eye diseases requiring steroid treatment until the condition resolves and the course of therapy is complete.

## **Contraindications to Vaccination During a Smallpox Emergency**

During a smallpox emergency, all contraindications to vaccination would be reconsidered in the light of the risk of smallpox exposure. Persons would be advised by public health authorities on recommendations for vaccination.

Careful screening is essential to minimize complications from the smallpox vaccine. If you have any questions about whether or not someone should receive the smallpox vaccine, visit the CDC website at [www.cdc.gov/smallpox](http://www.cdc.gov/smallpox).

For more information, visit [www.cdc.gov/smallpox](http://www.cdc.gov/smallpox), or call CDC at 800-CDC-INFO (English and Spanish) or 888-232-6348 (TTY).  
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