Smallpox Vaccine Contraindications and Screening

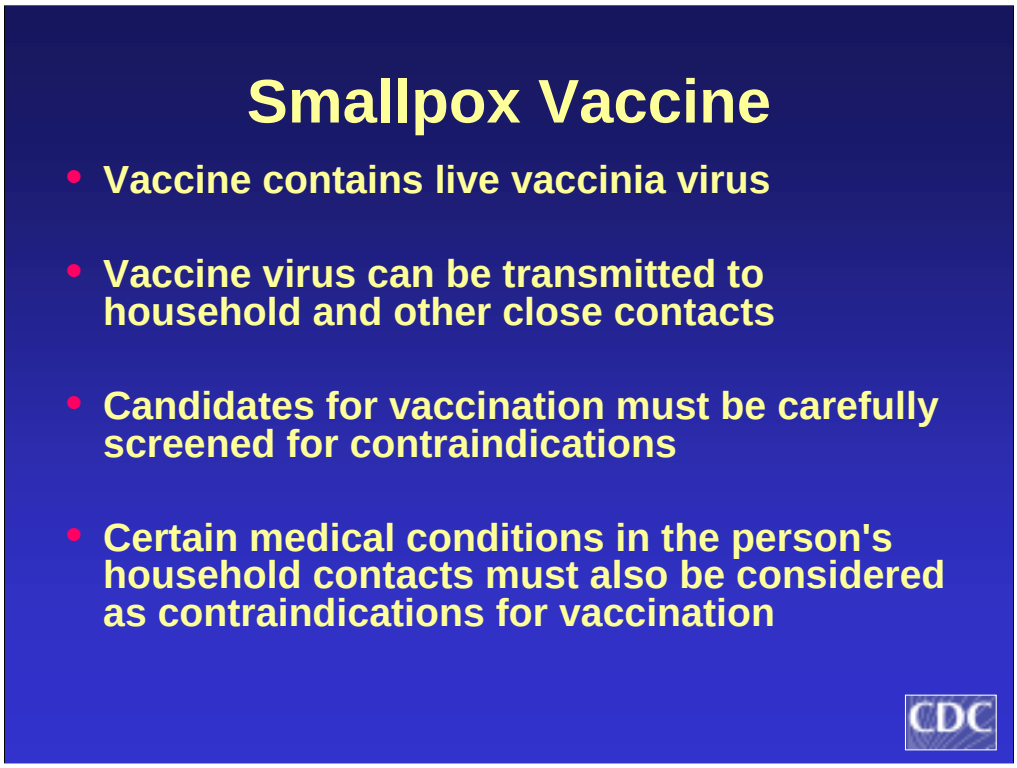
Department of Health and Human Services
Centers for Disease Control and Prevention
December 2002

Note: this graphic file is an expanded version of William Atkinson's on-air presentation, and contains both information presented on the broadcast as well as information on contraindications and precautions to vaccination included on the smallpox vaccine administration videotape.

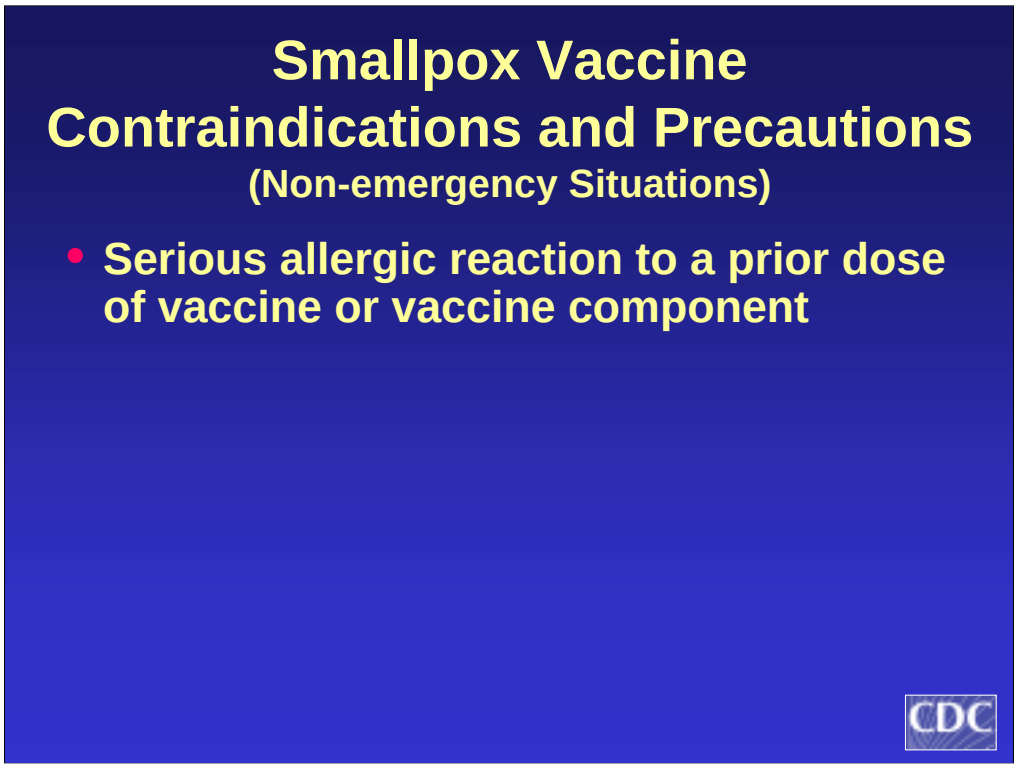
Smallpox Vaccine Contraindications and Screening

- Learning Objective:
  - Train clinic staff to screen potential vaccinees for contraindications of smallpox vaccine, including contraindications in potential vaccinees and in household contacts

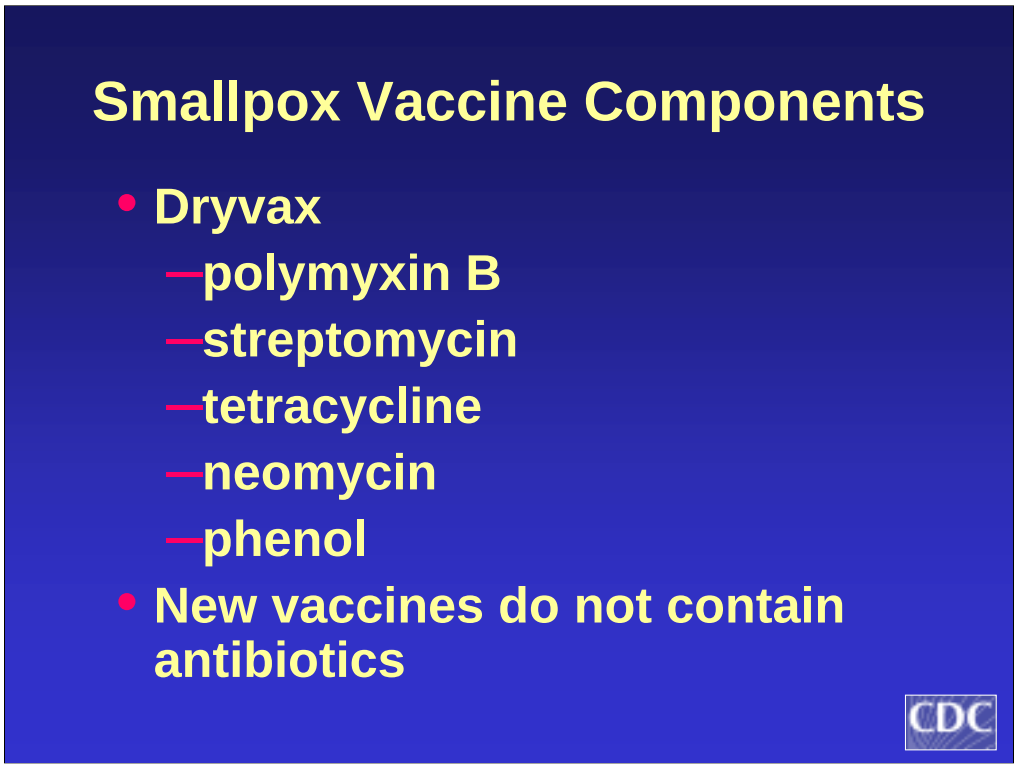
CDC



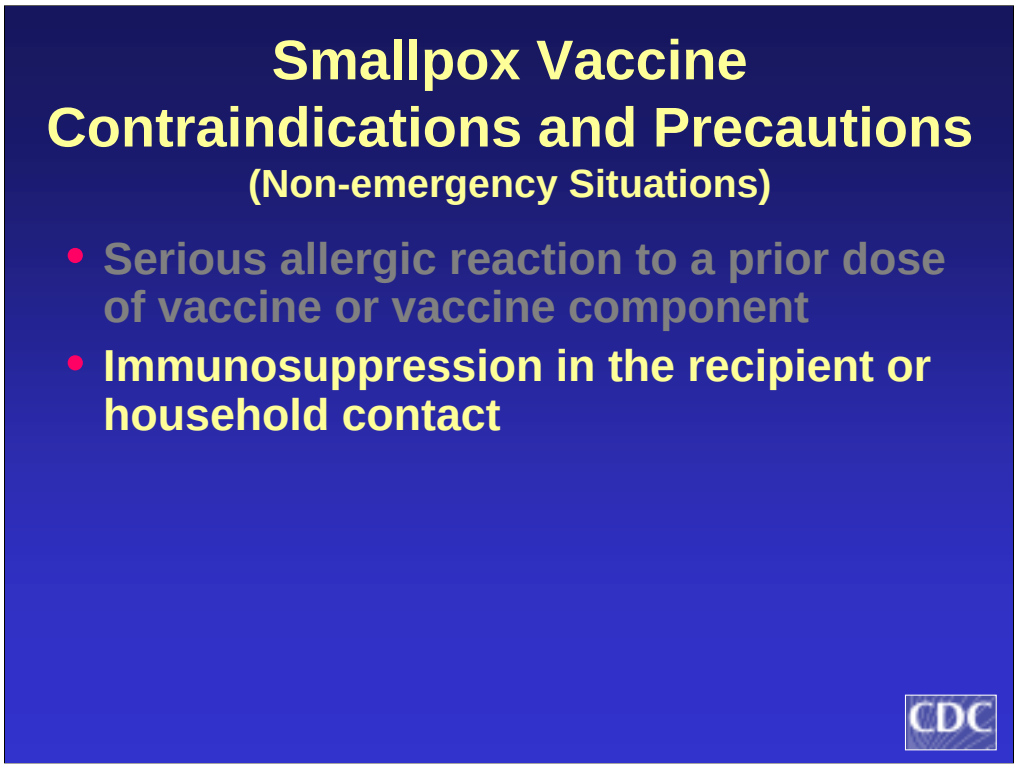
Skin lesion contains vaccine virus for up to 3 weeks.



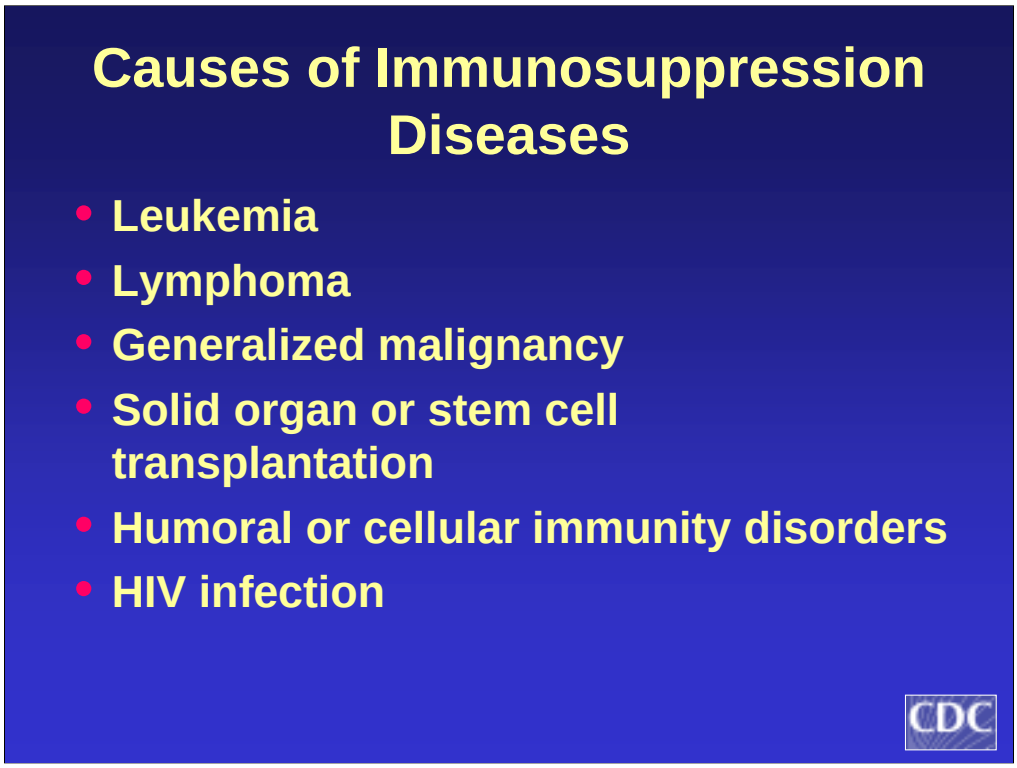
As with all vaccines, smallpox vaccine is contraindicated for persons who have experienced a serious allergic reaction to a prior dose of vaccine, or to a vaccine component. By serious allergic reaction, we mean anaphylaxis or symptoms of an anaphylaxis-like reaction, such as generalized urticaria, wheezing, or difficulty breathing



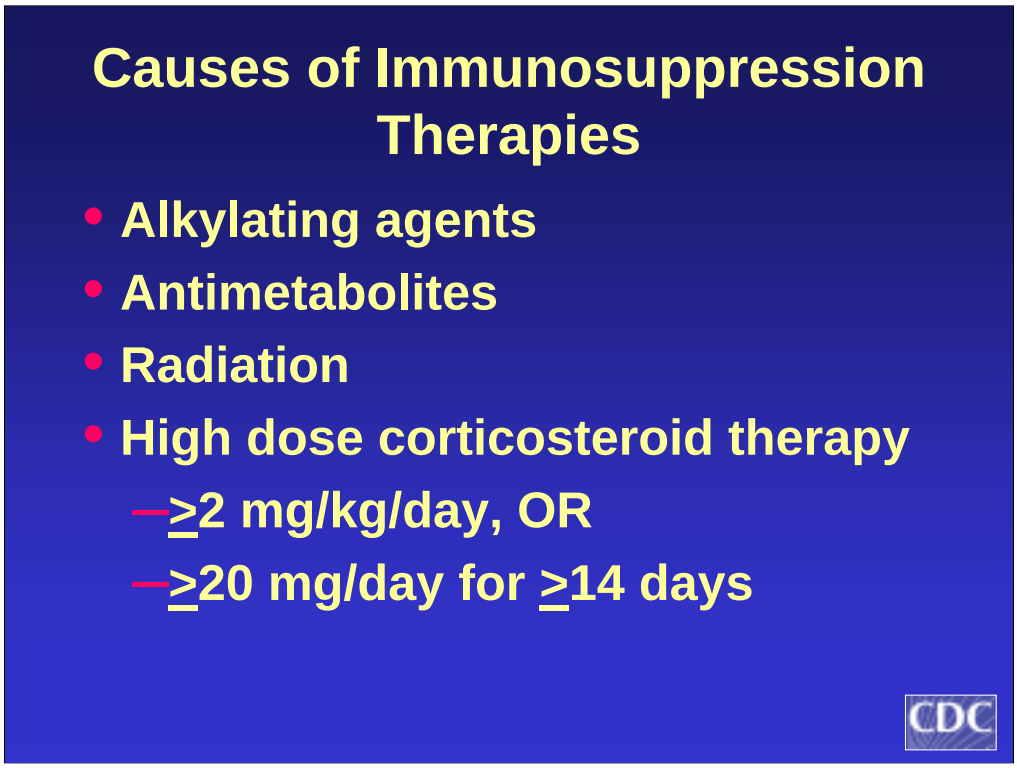
In addition to live vaccinia virus, The reconstituted Dryvax vaccine contains trace amounts of the antibiotics polymyxin B, streptomycin, tetracycline, and neomycin. It also contains, and phenol as a preservative. People with serious allergy to any of these products should not be vaccinated. The newer cell culture vaccines do not contain an antibiotics. No smallpox vaccine available in the United States contains sulfa-type antibiotics or penicillin.



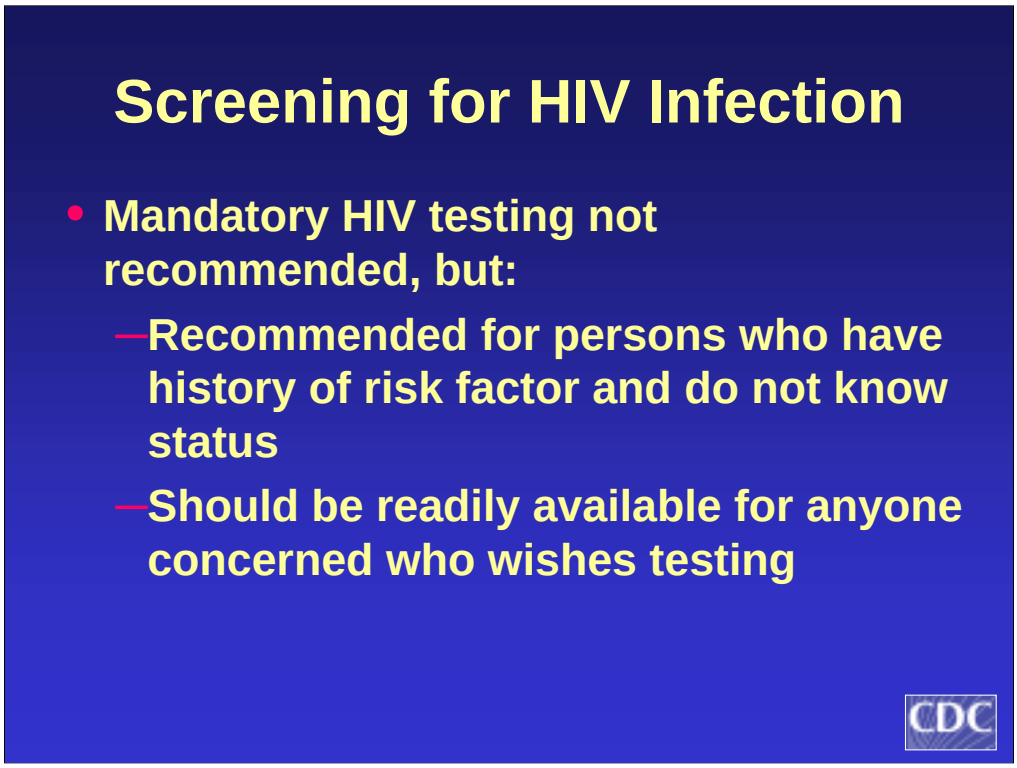
People with significant immunosuppression, should not receive smallpox vaccine. Replication of vaccinia virus can be enhanced among people with immunodeficiency diseases and immunosuppression, and result in serious adverse reactions. Also, because the recent vaccination site contains live virus that can be accidentally transmitted to other individuals, people with household contacts who are immunosuppressed should also not be vaccinated in non-emergency situations.



Significant immunosuppression can be caused by many diseases, including leukemia, lymphoma, generalized malignancy; solid organ or stem cell transplantation; and humoral or cellular immunity disorders, including HIV infection. Certain autoimmune diseases and/or treatment for autoimmune diseases may also be immunosuppressive.

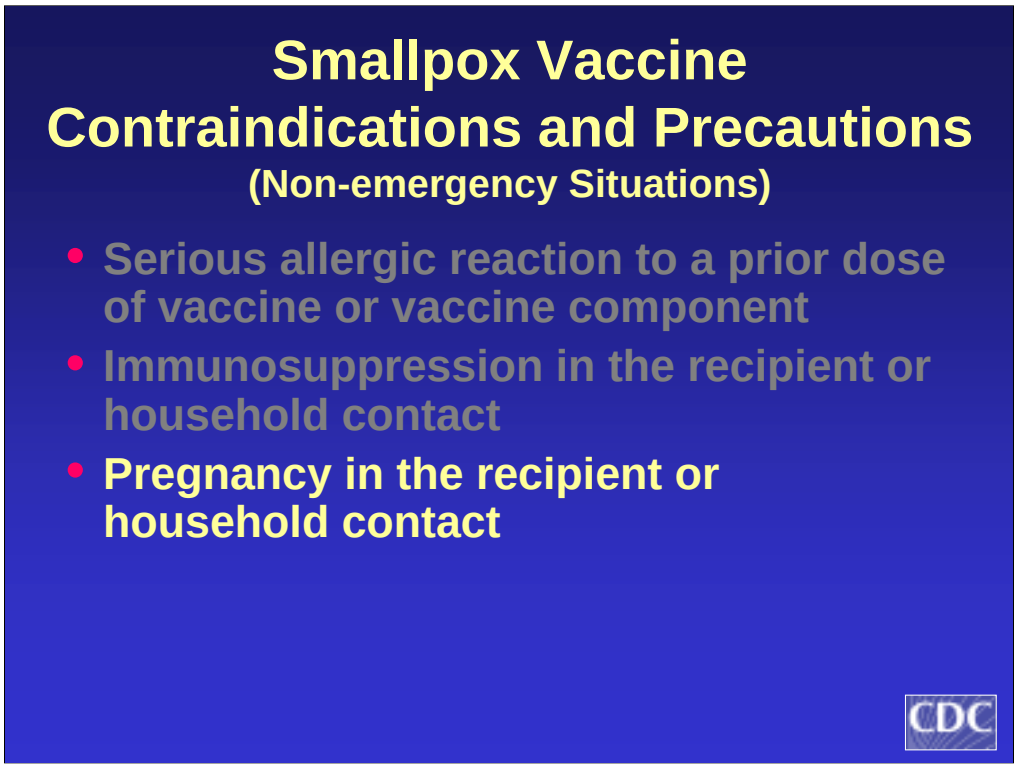


Therapies that can cause immunosuppression include alkylating agents, antimetabolites, radiation, or high dose corticosteroid therapy. Prednisone doses of 2 milligrams per kilogram of body weight per day or higher or 20 milligrams per day or higher for 14 days or more should be considered immunosuppressive. As with other live vaccines, those on high levels of these drugs should not be immunized for three months after their last dose.

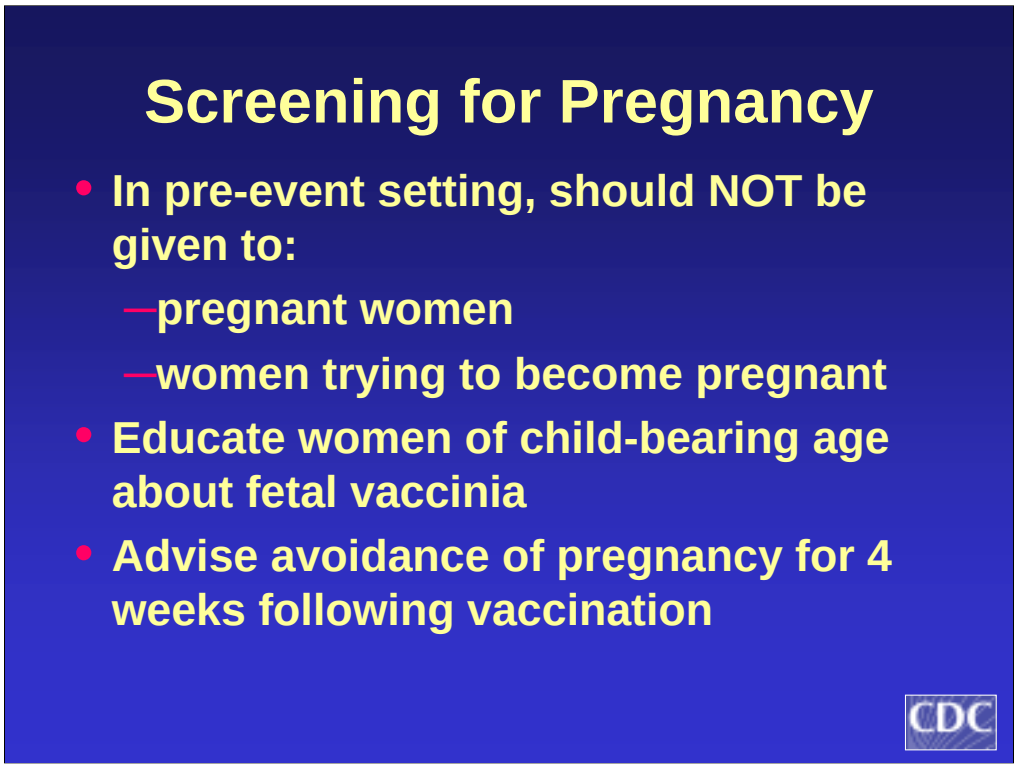


Persons with HIV infection or AIDS are at increased risk of progressive vaccinia (vaccinia necrosum) following vaccinia vaccination. Therefore, vaccinia vaccine should not be administered to persons with HIV infection or AIDS. Before vaccination, potential vaccinees should be educated about the risk of severe vaccinial complications among persons with HIV infection or other immunosuppressive conditions; persons who think they may have one of these conditions should not be vaccinated.

The ACIP does not recommend mandatory HIV testing prior to smallpox vaccination, but recommends that 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. Because known risk factors cannot be identified for some persons with HIV infection, 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 site for immunization. Information about local testing options should be provided to all potential vaccinees, including sites where testing is performed at no cost.



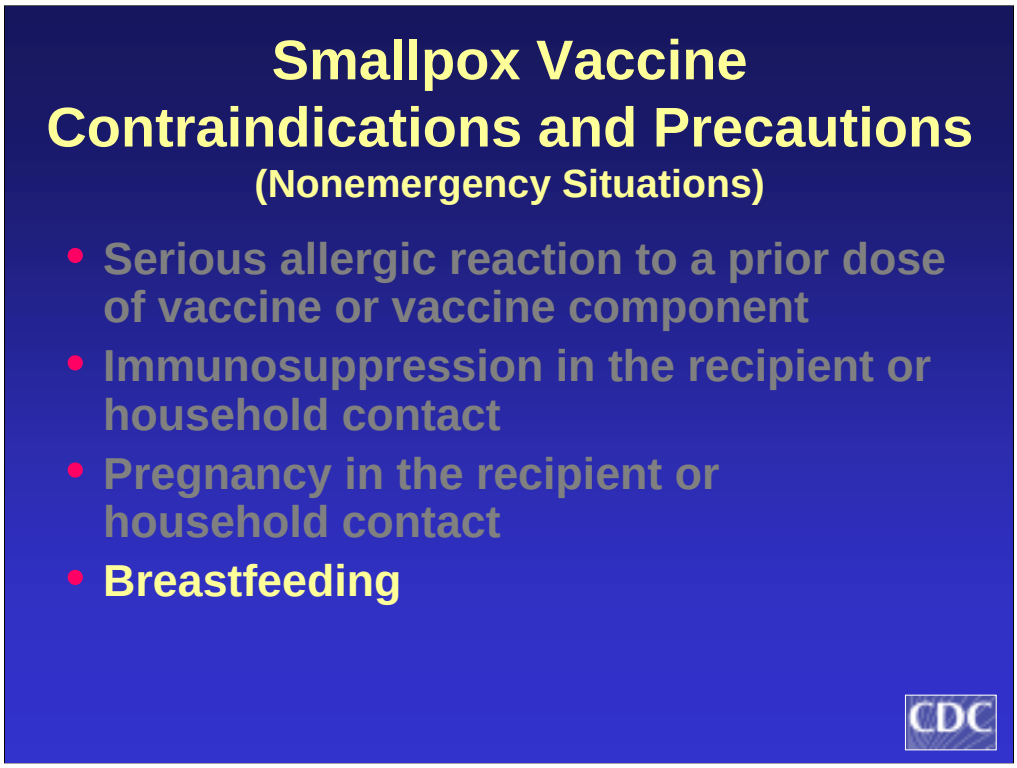
Live viral vaccines are contra indicated during pregnancy. So smallpox vaccine should not be administered to pregnant women or people with pregnant household contacts for non-emergency indications. Pregnancy should also be avoided for at least 4 weeks after vaccination. Pregnancy is a contraindication because of the risk of fetal vaccinia, a very rare complication of smallpox vaccination.



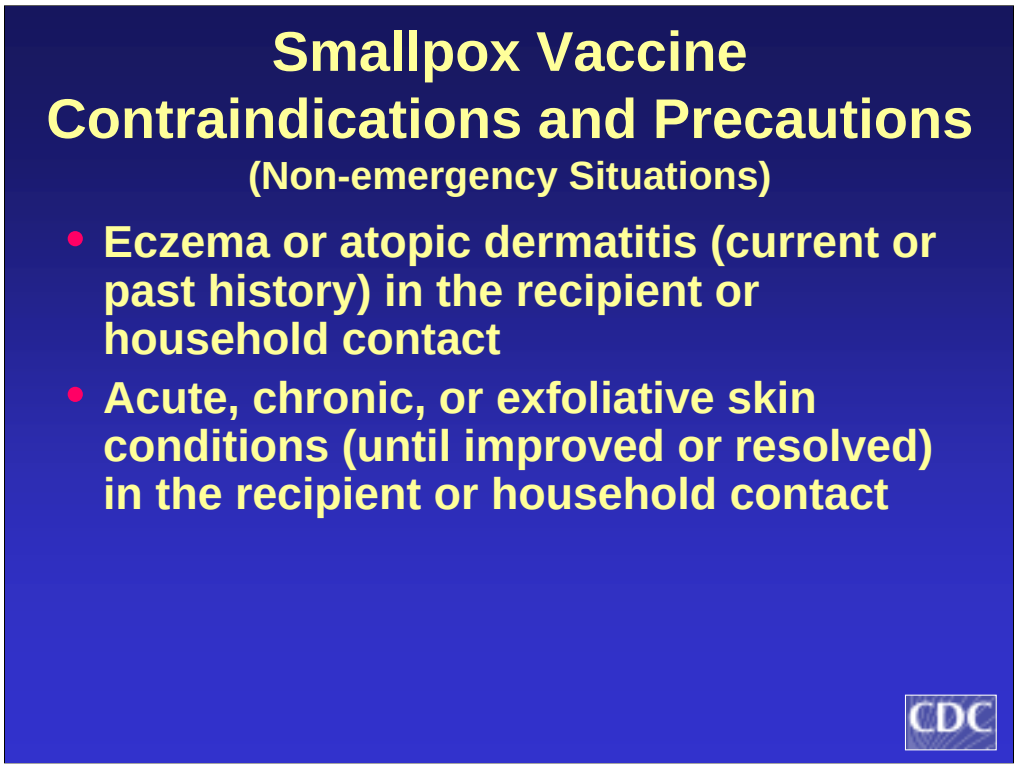
Fetal vaccinia is a very rare, but serious, complication of smallpox vaccination during pregnancy or shortly before conception. Therefore, vaccinia vaccine should not be administered in a pre-event setting to pregnant women or to women who are trying to become pregnant. Before vaccination, women of child-bearing 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 and women who are vaccinated counseled not to become pregnant during the 4 weeks after vaccination. Routine pregnancy testing of women of child-bearing age is not recommended.

To further reduce the risk of inadvertently vaccinating a woman who is pregnant, at the time of pre-screening, women of child-bearing age should be educated about fetal vaccinia, and abstinence or contraception to reduce the risk of pregnancy before or within four weeks after vaccination. Any woman who thinks she could be pregnant or who wants additional assurance that she is not pregnant should perform a urine pregnancy test with a “first morning” void urine on the day scheduled for vaccination. Such tests could be made available at the pre-screening and vaccination sites to avoid cost or access barriers to testing.

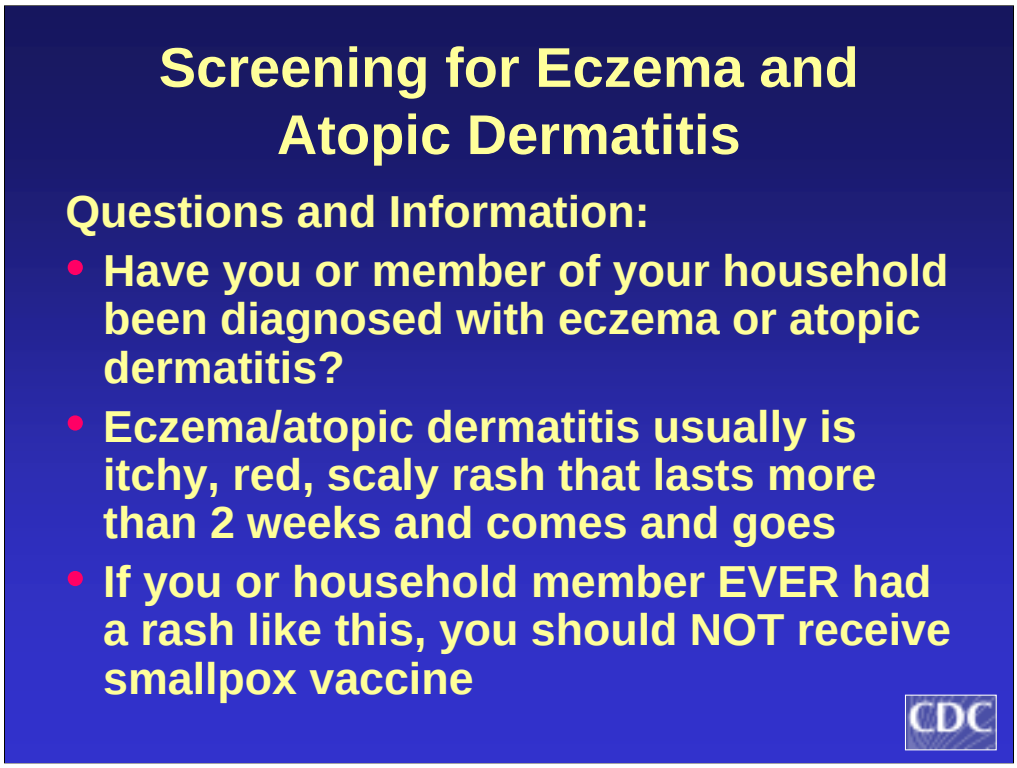
If a pregnant woman is inadvertently vaccinated or if she becomes pregnant within 4 weeks after vaccinia vaccination, she should be counseled regarding the basis of concern for the fetus. However, vaccination during pregnancy should not ordinarily be a reason to terminate pregnancy. To expand understanding of the risk of fetal vaccinia and to document whether adverse pregnancy outcome may be associated with vaccination, a pregnancy registry should be maintained and any adverse outcomes carefully investigated.



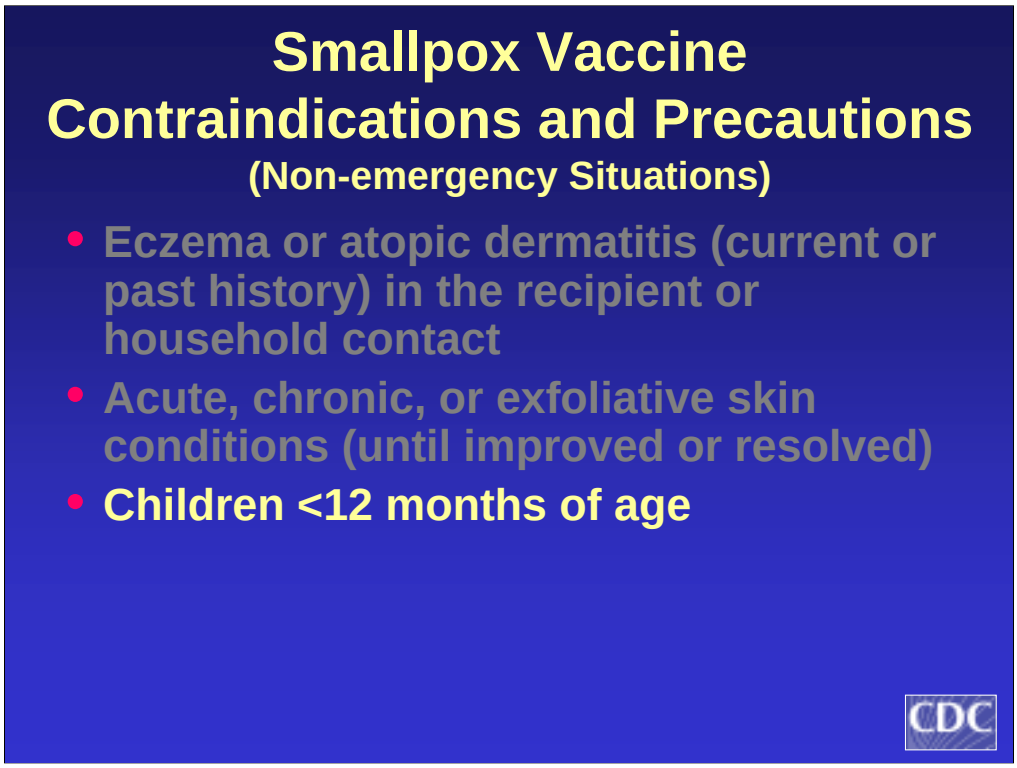
Breastfeeding is a contraindication because of the close contact and risk of contact transmission to the infant.



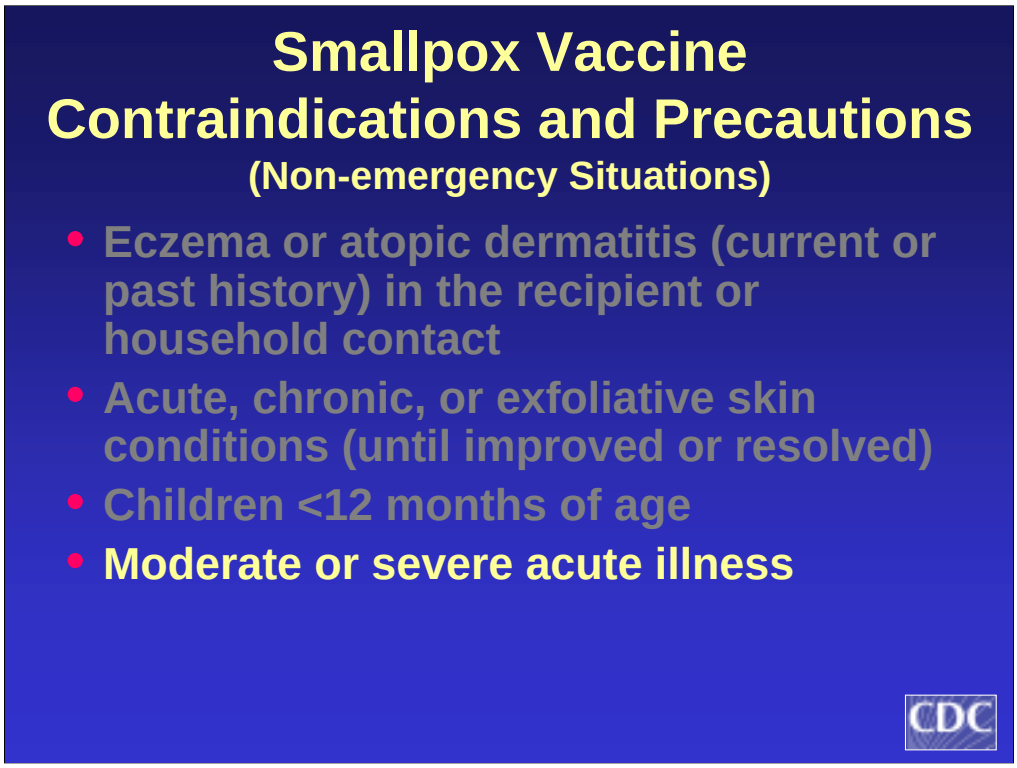
Because of the increased risk for eczema vaccinatum, smallpox vaccine should not be administered to people with eczema or atopic dermatitis or a past history of these conditions. People who have a HOUSEHOLD CONTACT with eczema or atopic dermatitis or a history of these conditions should also not be vaccinated. People with other types of acute, chronic, or exfoliative skin conditions, such as psoriasis, contact dermatitis, burns, impetigo, or herpes zoster might (shingles) be at higher risk for inadvertent inoculation from the vaccine. People with exfoliative skin conditions, or whose household contact has this condition should not be vaccinated until the condition resolves or is under good control or resolves.



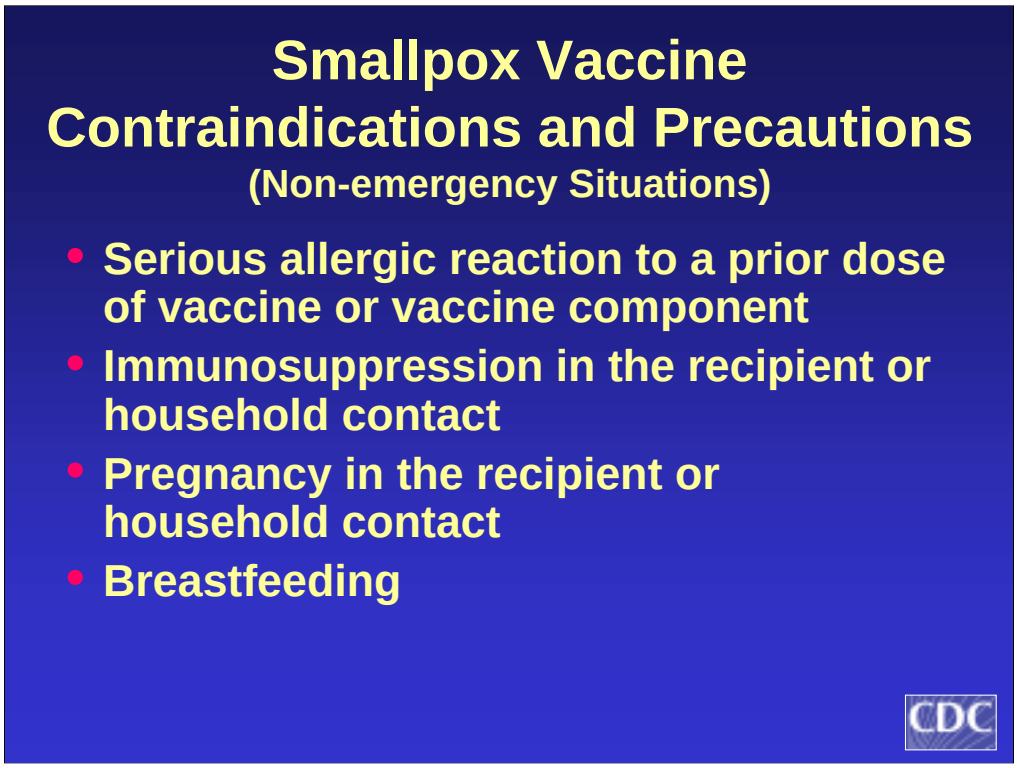
To assist providers in identifying persons that should defer smallpox (vaccinia) vaccination, the ACIP offers the following two screening questions: 1) Have you, or a member of your household ever been diagnosed with eczema or atopic dermatitis—if you answered "yes," you may NOT receive the smallpox (vaccinia) vaccine due to the risk that you or your household contact might develop a severe and potentially life-threatening illness called eczema vaccinatum; and 2) Eczema/atopic dermatitis usually is an itchy red, scaly rash that lasts more than 2 weeks and often comes and goes. If you or a member of your household have **ever** had a rash like this—you should NOT receive the smallpox (vaccinia) vaccine at this time unless you and a healthcare provider are sure that this rash is not atopic dermatitis or eczema. In cases where the dermatological risk factor or diagnosis is uncertain, some organizations, such as the military or CDC, may elect to develop more precise screening tools. These secondary screening tools should weigh the individual's risk of developing an adverse event with the requirement of occupational readiness through safe smallpox vaccination to ensure national security.



Children less than 12 months of age year should not be vaccinated. All vaccinated people should take precautions to prevent virus transmission to young children and other household contacts. Infants are at risk if post-vaccinial encephalitis if infected.



As with all vaccines, vaccination should be deferred for people with moderate or severe acute illnesses.



Summary slide

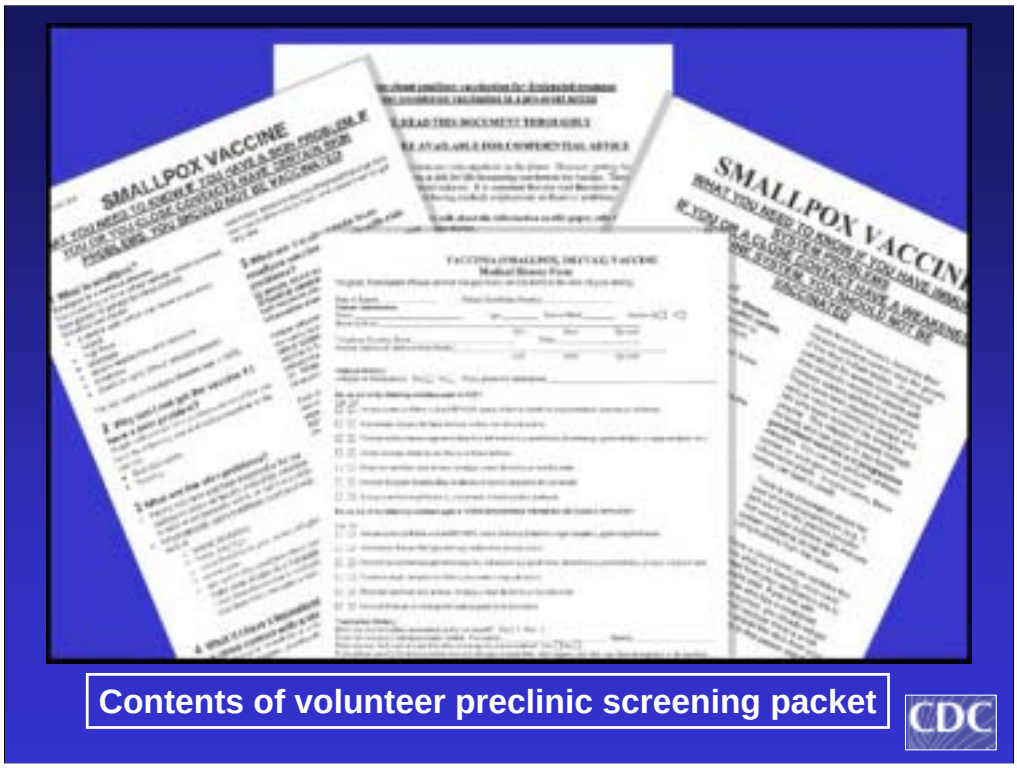
Smallpox Vaccine Contraindications and Precautions

(Non-emergency Situations)

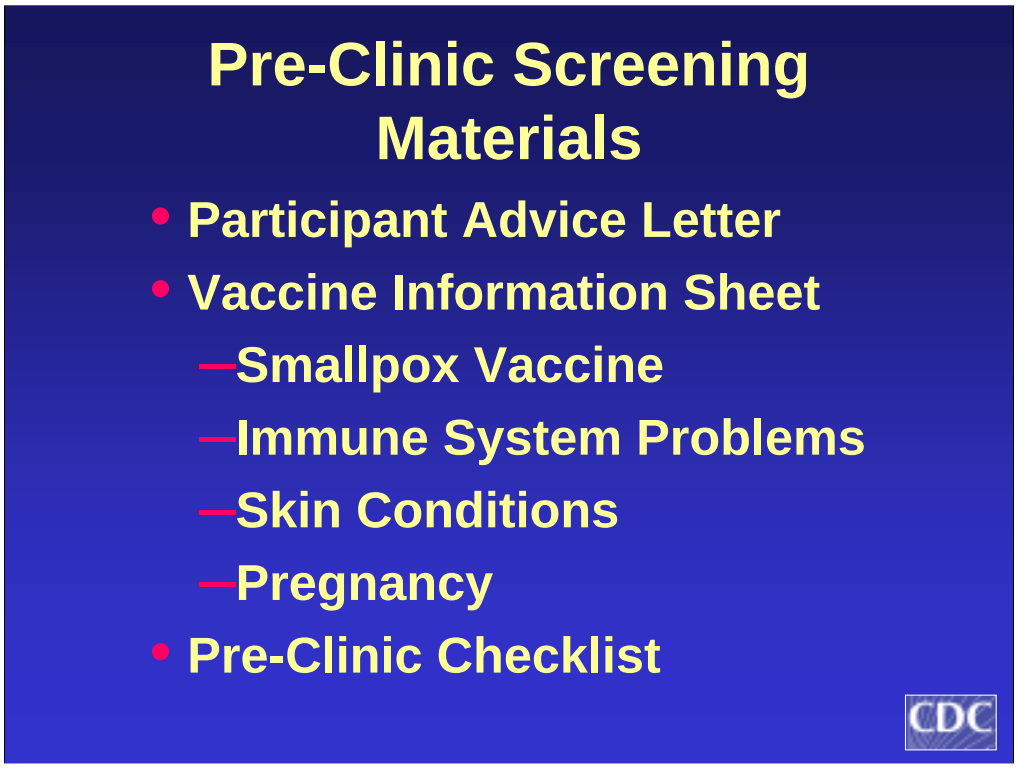
- Eczema or atopic dermatitis (current or past history) in the recipient or household contact
- Acute, chronic, or exfoliative skin conditions (until improved or resolved) in the recipient or household contact
- Children <12 months of age
- Moderate or severe acute illness

CDC

Summary slide



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.



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 event occur. Other written materials will include a Vaccine Information Statement on the smallpox vaccine and further detailed information statements about various contraindications; including immune system problems, skin conditions and pregnancy. And finally, they will be given a checklist asking them to screen themselves for possible contraindications. They will not turn this form in, but can use it as a further aid to help them decide whether or not they can take the vaccine.

For More Information

- CDC Smallpox website
  www.cdc.gov/smallpox

- National Immunization Program website
  www.cdc.gov/nip