



Frequently Asked Questions About Smallpox Vaccine

THE VACCINE

What is the smallpox vaccine, and is it still required?

The smallpox vaccine is the only way to prevent smallpox. The vaccine is made from a virus called *vaccinia*, which is another "pox"-type virus related to smallpox but cannot cause smallpox. The vaccine helps the body develop immunity to smallpox. It was successfully used to eradicate smallpox from the human population.

Routine vaccination of the American public against smallpox stopped in 1972 after the disease was eradicated in the United States. Until recently, the U.S. government provided the smallpox vaccine only to a few hundred scientists and medical professionals who work with smallpox and similar viruses in a research setting. After the events of September and October, 2001, however, the U.S. government took further actions to improve its level of preparedness against terrorism. For smallpox, this included updating a response plan and ordering enough smallpox vaccine to immunize the American public in the event of a smallpox outbreak. The plans are in place, and there is sufficient vaccine available to immunize everyone who might need it in the event of an emergency. In addition, in December of 2002, the Bush Administration announced a plan to better protect the American people against the threat of smallpox attack by hostile groups or governments. This plan includes the creation of smallpox healthcare teams that would respond to a smallpox emergency. Members of these teams are being vaccinated against smallpox. The plan also includes vaccination of certain military and civilian personnel who are or may be deployed in high threat areas. (updated Feb 24, 2003)

Should I get vaccinated against smallpox?

The smallpox vaccine is not available to the public at this time. (added Nov 13, 2002)

How is the vaccine given?

The smallpox vaccine is not given with a hypodermic needle. It is not a "shot," like many vaccinations. The vaccine is given using a bifurcated (two-pronged) needle that is dipped into the vaccine solution. When removed, the needle retains a droplet of the vaccine. The needle is then used to prick the skin a number of times in a few seconds. The pricking is not deep, but it will cause a sore spot and one or two drops of blood to form. The vaccine usually is given in the upper arm.

If the vaccination is successful, a red and itchy bump develops at the vaccination site in three or four days. In the first week after vaccination, the bump becomes a large blister, fills with pus, and begins to drain. During week two, the blister begins to dry up and a scab forms. The scab falls off in the third week, leaving a small scar. People who are being vaccinated for the first time may have a stronger "take" (a successful reaction) than those who are being revaccinated. (added Nov 13, 2002)

Many vaccinations are required. Why don't people have to get the smallpox vaccine?

The last case of smallpox in the United States was in 1949. The last naturally occurring case in the world was in Somalia in 1977. After the disease was eliminated from the world, routine vaccination against smallpox among the general public was stopped because it was no longer necessary for prevention. (added Nov 13, 2002)

If someone is exposed to smallpox, is it too late to get a vaccination?

Vaccination within 3 days of exposure will completely prevent or significantly modify smallpox in the vast majority of persons. Vaccination 4 to 7 days after exposure likely offers some protection from disease or may modify the severity of disease. (added Nov 13, 2002)

How long does a smallpox vaccination last?

Past experience indicates that the first dose of the vaccine offers protection from smallpox for 3 to 5 years, with decreasing immunity thereafter. If a person is vaccinated again later, immunity lasts longer. (added Nov 13, 2002)

Are diluted doses of smallpox vaccine as effective?

Recent tests have indicated that diluted smallpox vaccine is just as effective in providing immunity as full-strength vaccine. (updated Dec 9, 2002)

VACCINIA

What is the smallpox vaccine made of?

The vaccine is made from a virus called *vaccinia*, another "pox"-type virus related to smallpox but that does not cause smallpox. The smallpox vaccine helps the body develop immunity to smallpox. It does not contain the smallpox virus and cannot spread smallpox. (added Nov 13, 2002)

Is it possible for people to get smallpox from the vaccination?

No. The smallpox vaccine does not contain smallpox virus and cannot spread or cause smallpox. However the vaccine does contain another virus called *vaccinia*, which is "live" in the vaccine. Because the virus is live, it can spread to other parts of the body or to other people from the vaccine site. This can be prevented through proper care of the vaccination site (e.g., hand washing and careful disposal of used bandages). (added Nov 13, 2002)

Is it possible to get vaccinia, the virus in the vaccine, from someone who has recently been vaccinated?

Yes. *Vaccinia* is spread by touching a vaccination site before it has healed or by touching bandages or clothing that have become contaminated with live virus from the vaccination site. *Vaccinia* is not spread through airborne contagion. The *vaccinia* virus may cause rash, fever, and head and body aches. (updated Dec 9, 2002)

VACCINE SAFETY

How safe is the smallpox vaccine?

The smallpox vaccine is the best protection you can get if you are exposed to the smallpox virus. Most people experience normal, usually mild reactions that include a sore arm, fever, and body aches. In recent tests, one in three people felt bad enough to miss work, school, or recreational activity or had trouble sleeping after receiving the vaccine. However, the vaccine does have some risks. In the past, about 1,000 people for every 1 million people vaccinated for the first time experienced reactions that, while not life-threatening, were serious. These reactions include a vigorous (toxic or allergic) reaction at the site of the vaccination and spread of the *vaccinia* virus (the live virus in the smallpox vaccine) to other parts of the body and to other people. These reactions typically do not require medical attention. Rarely, people have had very bad reactions to the vaccine. In the past, between 14 and 52 people per 1 million vaccinated experienced potentially life-threatening reactions, including eczema vaccinatum, progressive *vaccinia* (or *vaccinia necrosum*), or postvaccinal encephalitis. Based on past experience, it is estimated that between 1 and 2 people out of every 1 million people vaccinated will die as a result of life-threatening reactions to the vaccine. Careful screening of potential vaccine recipients is essential to ensure that those at increased risk do not receive the vaccine.

People most likely to have side effects are people who have, or even once had, skin conditions, (especially eczema or atopic dermatitis) and people with weakened immune systems, such as those who have received a transplant, are HIV positive, or are receiving treatment for cancer. Anyone who falls within these categories, or lives with someone who falls into one of these categories, should NOT get the smallpox vaccine unless they are exposed to the disease. Pregnant women should not get the vaccine because of the risk it poses to the fetus. Women who are breastfeeding should not get the vaccine. Children younger than 12 months of age should not get the vaccine. Also, the Advisory Committee on Immunization Practices (ACIP) advises against non-emergency use of smallpox vaccine in children younger than 18 years of age. In addition, the vaccine manufacturer's package insert states that the vaccine is not recommended for use in geriatric populations in non-emergency situations. The term geriatric generally applies to those people age 65 and above. Also, people who are using steroid drops in their eyes should wait until they are no longer using the medication to get the vaccine. Also, people who have been diagnosed by a doctor as having heart disease with or without symptoms, including conditions such as previous myocardial infarction (heart attack), angina (chest pain caused by lack of blood flow to the heart), congestive heart failure, and cardiomyopathy, stroke or transient ischemic attack (a "mini-stroke" that produces stroke-like symptoms but no lasting damage), chest pain or shortness of breath with activity (such as walking up stairs), or other heart conditions being treated by a doctor should not get the vaccine at this time. (Heart disease may be a temporary exclusion and may change as more information is gathered.) In addition, individuals who have 3 or more of the following risk factors should not get the vaccine at this time: high blood pressure diagnosed by a doctor; high blood cholesterol diagnosed by a doctor; diabetes or high blood sugar diagnosed by a doctor; a first degree relative (for example, mother, father, brother or sister) with a heart condition before the age of 50; and/or, currently a cigarette smoker. (These may be temporary exclusions and may change as more information is gathered.)
(updated Mar 31, 2003)

Who should NOT get the vaccine?

People who should not get the vaccine include anyone who is allergic to the vaccine or any of its components (polymyxin B, streptomycin, chlortetracycline, neomycin); pregnant women; women who are breastfeeding; people who have, or have had, skin conditions (especially eczema and atopic dermatitis); and people with weakened immune systems, such as those who have received a transplant, are HIV positive, are receiving treatment for cancer, or are taking medications (like steroids) that suppress the immune system. Also individuals younger than 12 months of age should not get the vaccine. Additionally, the Advisory Committee on Immunization Practices (ACIP) advises against non-emergency use of smallpox vaccine in children younger than 18 years of age and the vaccine manufacturer's package insert states that the vaccine is not recommended for use in geriatric populations in non-emergency situations. The term geriatric generally applies to those people age 65 and above. These people should not receive the vaccine unless they have been exposed to smallpox. Also, people who are using steroid drops in their eyes should wait until they are no longer using the medication to get the vaccine. In addition, people who have been diagnosed by a doctor as having a heart condition with or without symptoms, including conditions such as previous myocardial infarction (heart attack), angina (chest pain caused by lack of blood flow to the heart), congestive heart failure, and cardiomyopathy, stroke or transient ischemic attack (a "mini-stroke" that produces stroke-like symptoms but no lasting damage), chest pain or shortness of breath with activity (such as walking up stairs), or other heart conditions being treated by a doctor should not get the vaccine at this time. In addition, individuals who have 3 or more of the following risk factors should not get the vaccine at this time: high blood pressure diagnosed by a doctor; high blood cholesterol diagnosed by a doctor; diabetes or high blood sugar diagnosed by a doctor; a first degree relative (for example, mother, father, brother or sister) with a heart condition before the age of 50; and/or, currently a cigarette smoker. (These may be temporary exclusions and may change as more information is gathered.)
(updated Mar 31, 2003)

Should you get the smallpox vaccine if you have a weakened immune system (e.g., you are immunocompromised)?

No, you should not be vaccinated, unless there is a smallpox outbreak and you have been directly exposed to the smallpox virus. Vaccination can cause death in people with weakened immune systems. Thus, there is no need to take the risks associated with smallpox vaccination unless you have been directly exposed to smallpox—and even then, you should first consult a physician or health care provider. (added Nov 13, 2002)

Pregnant women are discouraged from getting the vaccine. Is there a danger to them (or to an unborn child) if broader vaccination occurs, increasing the potential for contact with vaccinated people?

Pregnant women should NOT be vaccinated in the absence of a smallpox outbreak because of risk of fetal infection. Inadvertent transmission of vaccinia virus to a pregnant woman could also put the fetus at risk. Vaccinated persons must be very cautious to prevent transmission of the vaccine virus to pregnant women or other contacts. (added Nov 13, 2002)

Why has CDC advised that people with known cardiac disease not receive the smallpox vaccine?

CDC has received reports of cardiac events following smallpox vaccinations. Although it is unclear whether or not there is any association between smallpox vaccination and these events, CDC recommends, as a precautionary measure, that individuals who have been diagnosed by a doctor as having a heart condition with or without symptoms should not receive smallpox vaccine at this time. These include conditions such as: previous myocardial infarction (heart attack), angina (chest pain caused by lack of blood flow to the heart), congestive heart failure and cardiomyopathy, stroke or transient ischemic attack (a “mini-stroke” that produces stroke-like symptoms but no lasting damage), chest pain or shortness of breath with activity (such as walking up stairs), or other heart conditions being treated by a doctor should not get the vaccine at this time. In addition, individuals who have 3 or more of the following risk factors should not get the vaccine at this time: high blood pressure diagnosed by a doctor; high blood cholesterol diagnosed by a doctor; diabetes or high blood sugar diagnosed by a doctor; a first degree relative (for example, mother, father, brother or sister) with a heart condition before the age of 50; and/or, currently a cigarette smoker. These may be temporary exclusions and may change as more information is gathered. The presence of these conditions in a close contact is not a reason to defer vaccination. Vaccination of other persons should be continued as planned. (Updated Mar 31, 2002)

What is CDC doing to respond to reports of cardiac-related events?

CDC recommends, as a precautionary measure, that people who have been diagnosed by a doctor as having a heart condition with or without symptoms should not get the smallpox vaccine at this time while experts continue their investigation. This would include conditions such as previous myocardial infarction (heart attack), angina (chest pain caused by a lack of blood flow to the heart), congestive heart failure and cardiomyopathy, stroke or transient ischemic attack (a “mini-stroke” that produces stroke-like symptoms but no lasting damage), chest pain or shortness of breath with activity (such as walking up stairs), or other heart conditions being treated by a doctor. In addition, individuals who have 3 or more of 5 specific risk factors are being told to defer vaccination for the time being. These risk factors are: high blood pressure diagnosed by a doctor; high blood cholesterol diagnosed by a doctor; diabetes or high blood sugar diagnosed by a doctor; a first degree relative (for example, mother, father, brother or sister) with a heart condition before the age of 50; and/or, currently a cigarette smoker. This exclusion may be removed as more information becomes available.

In addition, in response to reports of myopericarditis, CDC sent out health alert messages for partners and clinicians; has issued a supplement to the vaccine information statement (VIS) that alerts potential vaccinees to this new potential adverse event; has issued a supplement to the pre-vaccination screening worksheet to screen for the presence of the conditions listed above; has developed a fact sheet for recent

vaccinees on this issue, has updated the history and consent form, is amending the adverse event monitoring systems to include myopericarditis and is developing additional strategies to prospectively assess the incidence of cardiac events among vaccine recipients. In response to reports of severe coronary events, CDC is updating the ACIP Vaccine Safety Working Group and alerting the public about the death; obtaining consultation from cardiologists and other experts; assessing the expected age-adjusted death rate for the vaccination population; and assessing the causal relationship between vaccination and serious cardiac events. (Updated Mar 31, 2002)

Is there any way to treat bad reactions to the vaccine?

Vaccinia Immune Globulin (VIG) can help people who have certain serious reactions to smallpox vaccine. A second drug, cidofovir, may be used in some situations. Neither drug is currently licensed for this purpose (both administered under investigational new drug (IND) protocol) and they may have side effects of their own. (updated Feb 24, 2003)

Is a child under the age of 1 year in the household a contraindication to vaccination?

No, the presence of a child under the age of 1 year in the household is not a contraindication to vaccination. The Advisory Committee on Immunization Practices (ACIP) met on January 14, 2003 to consider, among several issues, the question of whether a child under the age of 1 year in the household should be added to the conditions or situations that are considered a contraindication to smallpox vaccination. A vote was taken and it was confirmed that the presence of an infant in the household is not a contraindication to vaccination. Approved language from this meeting on this subject was: *"The ACIP does not recommend vaccination of children and adolescents less than 18 years in the current pre-vaccination program, and smallpox vaccine is contraindicated for infants less than 1 year of age. The presence of an adolescent or child (including an infant) in the household, however, is not a contraindication to vaccination of other members of the household. Data suggests that the risk of serious complications from transmission from an adult to a child is extremely small. However, the ACIP recognizes that some programs may defer vaccination of household contacts of infants less than 1 year of age because of data suggesting a higher risk of adverse events among primary vaccinees in this age group, compared with that among older children."* Vaccinated parents of young children need to be careful not to inadvertently spread the virus to their children. They should follow site care instructions that are essential to minimizing the risk of contact transmission of vaccinia. These precautions include covering the vaccination site, wearing a sleeved shirt, and careful hand washing anytime after touching the vaccination site or anything that might be contaminated with virus from the vaccination site. If these precautions are followed, the risk for children is very low. Individuals who do not believe that they can adhere to such instructions should err on the side of caution and not be vaccinated at this time. (added Jan 29, 2003)

Are there any eye conditions that would preclude vaccination?

The concern surrounding eyes is that frequent touching of the eyes by someone who has gotten the smallpox vaccine may increase the chances that that person will experience spread of the vaccinia virus to the eyes (inadvertent inoculation of the eye) by touching the vaccine site or something contaminated with live virus and then touching their eyes before they wash their hands. This side effect is a serious one because it can lead to damaged vision, or even blindness. People who wear contact lenses, or touch their eyes frequently throughout the day can get the smallpox vaccine, but they must be especially careful to follow instructions for care of the smallpox vaccination site. Frequent and thorough hand washing will minimize the chance of contact spread of the vaccinia virus. As an additional precaution to minimize the risk of this type of transmission in selected groups of people, on January 14, 2003, the Advisory Committee on Immunization Practices (ACIP) decided that anyone with eye diseases or other conditions (e.g. recent LASIK surgery) that require the use of corticosteroid drops in the eye should wait until they no longer require such treatment before getting vaccinated. (added Jan 29, 2003)

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

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