

# SMALLPOX VACCINE

## WHAT YOU NEED TO KNOW

### 1 What is smallpox?

Smallpox is a serious disease which kills up to 30% of people infected with it.

It is caused by a virus called **variola**, which is spread from person to person through close contact.

Smallpox can also cause:

- a severe rash, which can leave scars when healed
- high fever
- tiredness
- severe headaches and backache
- blindness

The world's last case of naturally-acquired smallpox was in 1977.

### 2 Why get vaccinated?

Smallpox vaccine protects people who work with smallpox or related viruses in laboratories.

It is believed that terrorists or governments hostile to the United States might also have the smallpox virus and could use it as a biological weapon. Smallpox vaccination can protect health care response teams, and other first responders, from smallpox disease. These teams will identify other people who need to be vaccinated to control outbreaks, and establish public vaccination clinics.

During an outbreak or emergency, smallpox vaccine can protect people exposed to smallpox virus.

### 3 Smallpox vaccine

Smallpox vaccine is made from a virus called **vaccinia**. Vaccinia virus is similar to smallpox virus, but less harmful. Vaccinia vaccine can protect people from smallpox. The vaccine does not contain smallpox virus.

Getting the vaccine *before* exposure will protect most people from smallpox. Getting the vaccine *within 3 days after exposure* can prevent the disease or at least make it less severe. Getting the vaccine *within a week after exposure* can still make the disease less severe. Protection from infection lasts 3 to 5 years, and protection from severe illness and death can last 10 years or more.

### 4 Who should get smallpox vaccine and when?

#### Routine Non-emergency Use (No Outbreak)

- Laboratory workers who handle cultures or animals contaminated or infected with vaccinia or other related viruses (e.g., monkeypox, cowpox, variola).
- Public health, hospital, and other personnel, generally 18-65 years of age, who may have to respond to a smallpox case or outbreak.

#### Emergency Use (Smallpox Outbreak)

- Anyone *directly exposed* to smallpox virus should get one dose of vaccine as soon as possible after exposure.
- Anyone *at risk of exposure* to smallpox virus may need to get one dose of vaccine when the risk occurs or becomes known.

*Vaccinated persons may need to be revaccinated after 3-10 years, depending on risk.*

### 5 After the vaccination

*See VIS Supplements A and B for more information.*

#### Expected Reactions

A blister should form at the vaccination site. Later it will form a scab. Finally the scab will fall off, leaving a scar.

You may also experience swelling and tenderness of the lymph nodes lasting 2-4 weeks after the blister has healed, itching at the vaccination site, fatigue, mild fever, headache, or muscle aches.

#### Care of the Vaccination Site

**Until the scab falls off, you can spread vaccinia virus to other people or to other parts of your own body.**

To prevent this, keep this area loosely covered with a gauze bandage. (While at work, health care workers will need additional measures, such as a semi-permeable dressing covering the gauze.)

Change the bandage as needed (every 1-3 days if using only gauze bandages, and at least every 3-5 days for semi-permeable dressings). Cover with a waterproof

Continued . . .

bandage while bathing. Don't touch the vaccination site and then another part of your body without washing your hands first. Don't scratch or put ointment on the vaccination site. **Don't touch your eyes or any part of your body after changing the bandage or touching the vaccination site.**

Wear a shirt that covers the vaccination site as an extra precaution, particularly in situations of close physical contact (for instance, parenting of young children).

Put used bandages in a plastic zip bag before throwing them away. Do the same with the scab when it falls off. Don't share towels. Launder items that have touched the vaccination site. Wash your hands after touching the vaccination site or bandages, clothing, sheets or towels that have touched the site.

**The vaccination site should be checked at around 7 days after the vaccination to make sure the vaccine is working.**

**6**

**Some people should not get smallpox vaccine or should wait.**

*See VIS Supplements C, D, and E for more information.*

#### **Routine Non-emergency Use (No Outbreak)**

- Anyone who has eczema or atopic dermatitis, or has a past history of either condition, should not get smallpox vaccine.
- Anyone with a skin condition *that causes breaks in the skin* (such as an allergic rash, severe burn, impetigo, chickenpox, shingles, or severe acne) should wait until the condition clears up before getting smallpox vaccine.
- Anyone whose immune system is weakened should not get smallpox vaccine, including anyone who:
  - Has HIV/AIDS or another disease that affects the immune system.
  - Has significant immune system suppression from a severe autoimmune disease, such as systemic lupus erythematosus.
  - Is being treated, or has recently been treated, with drugs that affect the immune system, such as steroids, some drugs for autoimmune disease, or drugs taken in association with an organ or bone marrow transplant.
  - Has leukemia, lymphoma, or most other cancers.
  - Is taking cancer treatment with x-rays or drugs, or has taken such treatment in the past 3 months.

- Pregnant women should not get smallpox vaccine.

- Women should avoid getting pregnant for 4 weeks after getting smallpox vaccine.

***Individuals who live with or have close physical contact with someone who falls into any of the above categories should not get smallpox vaccine, because of the risk it poses to that close contact. (Close contacts include anyone living in your household and anyone you have close physical contact with, such as a sex partner. They do not include friends or people you work with.)***

- Smallpox vaccine is not recommended for anyone under 18 years of age.
- Do not get smallpox vaccine if you have ever had a life-threatening allergic reaction to **polymyxin B, streptomycin, chlortetracycline, neomycin, or a previous dose of smallpox vaccine.**
- Breastfeeding mothers should not get smallpox vaccine.
- Persons using steroid drops in their eyes should not get smallpox vaccine.
- People who are moderately or severely ill at the time the vaccination is scheduled should usually wait until they recover before getting smallpox vaccine.

**If you have questions about any of the conditions described above, consult with your health care provider before getting smallpox vaccine.**

#### **Emergency Use (Smallpox Outbreak)**

- These restrictions may not apply in the event of a smallpox outbreak.

**7**

**What are the risks from smallpox vaccine?**

*See VIS Supplement A for more information.*

The following information is about **known** reactions to smallpox vaccine. A vaccine, like any medicine, can cause serious problems, including those we do not yet know about, as well as severe allergic reactions. The risk of smallpox vaccine causing serious harm, or death, is very small.

#### **Mild to Moderate Problems**

- Mild rash, lasting 2-4 days.
- Fever of over 100°F (about 10% of adults).
- Blisters elsewhere on the body (about 1 per 1,900).

*About one-third of people getting the vaccine may feel sick enough to miss work or school or curtail recreational activities, or may have temporary trouble sleeping.*

Continued . . .

## Moderate to Severe Problems (That Need Immediate Medical Attention)

- Eye infection due to spread of vaccine virus to the eye, which can lead to loss of vision.
- Rash on entire body (as many as 1 per 4,000), which usually resolves without problems.

## Potentially Life-Threatening Problems

- Severe rash on people with eczema or atopic dermatitis (as many as 1 per 26,000), which can lead to scarring or death.
- Encephalitis (severe brain reaction) (as many as 1 per 83,000), which can lead to permanent brain damage or death.
- Severe progressive infection beginning at the vaccination site (as many as 1 per 667,000, mostly people with weakened immune systems), which can lead to scarring or death.

**For every million people vaccinated in the past, between 14 and 52 had a life-threatening reaction to smallpox vaccine and 1-2 died.**

*People who come in direct contact with the vaccination site of a vaccinated person, or with materials that have touched the site, also can have a reaction if they become infected with the vaccine virus.*

**8**

## What if there is a moderate or severe reaction?

*See VIS Supplements A and B for more information.*

### Look for:

- A vaccination site that looks like it is not healing normally, a rash or sore on other parts of your body, an eye infection, a persistent headache or fever, confusion, seizures, difficulty staying awake, or another unexpected problem. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness occurring within a few minutes to a few hours after the vaccination.

**If you, or a close physical contact, experience any of these conditions, or if you are concerned about any condition that you experience after vaccination:**

- Call a health care provider, or get the person medical care right away.
- Tell the health care provider that you were vaccinated with smallpox vaccine and when.

- Ask your doctor or nurse to file a Vaccine Adverse Event Report (VAERS form) and contact their health department. You can also file a report yourself by visiting the VAERS website at <http://www.vaers.org> or calling 1-800-822-7967.

## Treating Serious Reactions

- 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, and they may have side effects of their own.

## Cost of Treating Vaccine Reactions

- Treatment of severe reactions can be very expensive. Workers compensation or health insurance may not cover these expenses.
- There is no federal program to reimburse you for time lost from work, either because of illness due to vaccination or concern about spreading the virus to others. Your employer can tell you if they, or workers compensation, will cover these expenses.

**9**

## How can I learn more?

- Read the VIS Supplements.
- Ask your doctor or nurse. They can show you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-888-246-2675** (English)
  - Call **1-888-246-2857** (Español)
  - Call **1-866-874-2646** (TTY)
  - Visit our smallpox website at <http://www.cdc.gov/smallpox/>



**U.S. Department of Health & Human Services**  
Centers for Disease Control and Prevention  
National Immunization Program

Smallpox (1/16/03)

Vaccine Information Statement