



Smallpox Pre-Vaccination Information Packet: Contents and Instructions

The following information is for state and hospital personnel implementing smallpox vaccination programs.

Contents

- 1. Cover Letter** – A letter from Dr. Julie Louise Gerberding, M.D., MPH., Director of the Centers for Disease Control and Prevention (CDC) to potential vaccinees explaining the purpose of the national smallpox preparedness program, encouraging individuals to know their health status and to err on the side of caution in making their vaccination decision and detailing the contents of the Smallpox Pre-Vaccination Information Packet.
- 2. Smallpox Vaccine Information Statement (VIS)** - This document, entitled "Smallpox Vaccine: What You Need to Know," contains information about smallpox disease, the benefits and risks of smallpox vaccine, contraindications, vaccination site care instructions, what to do if a reaction occurs after vaccination, and where to get more information.
- 3. Pre-Event Screening Worksheet for Smallpox Vaccine** – a worksheet with questions to help individuals determine whether or not they should receive smallpox vaccine because of certain medical conditions that would place them at a greater risk for an adverse reaction from the vaccine. Some of these questions are of a personal and sensitive nature. Those implementing smallpox vaccination clinics should be prepared to discuss, but not collect, this sheet.
- 4. Someone You are Close to May Get Smallpox Vaccine: What You Should Know and Do** - a fact sheet that informs close contacts of people considering vaccination about the health conditions that put people at risk if they are in close physical contact with someone who has been vaccinated. This sheet also provides information about the steps close contacts can take to protect themselves.
- 5. Smallpox Vaccine: Decision Point for the Smallpox Vaccine Candidate** – a short video intended as an overview for use at vaccination clinic sites to supplement the written materials listed above.
- 6. Patient Medical History and Consent Form** – a form for clinic personnel to record patient information. The form also confirms the absence of contraindications and contains a consent signature line for the patients. This document **must be retained by the clinic** for 5 years or the length of time required by state law, whichever is longer.
- 7. Temporary Proof of Vaccination and Site Check Reminder Sheet** – This form serves as temporary proof of vaccination, contains follow-up appointment information, and provides vaccine recipients with a phone number to call if they think they are having an adverse reaction to the vaccine.

Instruction for Use

This package of materials is to be used as part of the national smallpox preparedness program to help ensure that potential vaccinees are adequately informed of the benefits and risks of smallpox vaccination, to assist in screening out individuals who should not receive the vaccine, and to obtain signed consent from those individuals who receive smallpox vaccine. In particular circumstances as provided by law, the federal government may assume liability for injury or death attributable to a smallpox vaccination. The materials contained in this packet fulfill federal obligations to inform vaccinees about the risks and benefits of the smallpox vaccine. **Use of the items in this packet as instructed below is mandatory. Do NOT alter the materials or replace them with alternative documents.**

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- **Provide items 1, 2, 3, and 4** to potential vaccinees as early as possible **before they make an appointment for vaccination**. Potential vaccinees should be given adequate time to obtain HIV or pregnancy testing, discuss contraindications with household contacts, talk to their health care providers, and check medical records.
- **Provide items 1-4** again to persons **when they present to the clinic** to receive smallpox vaccination. Give all individuals an opportunity to read the materials and view the "Decision Point" video (**item 5**) **before they consent to be vaccinated**. Offer to read the documents for individuals, especially if you suspect that they have difficulty understanding the material due to reading ability or language barriers. **Questions and concerns should be elicited from potential vaccinees and addressed by a trained health care provider.**
- Use the Patient Medical History and Consent Form (**item 6**) to confirm the absence of contraindications. Obtain signed consent and date on this form from all vaccinees. This document **must be retained by the clinic** for 5 years or the length of time required by state law, whichever is longer.
- Following immunization, provide vaccinees the Temporary Proof of Vaccination and Site Check Reminder Sheet (**item 7**). Clinic sites should insert local or state telephone numbers for adverse event reporting.
- Provide vaccinees a record of immunization following vaccination site examinations. It is the responsibility of each state to determine what type of permanent record of immunization they will use. Adult immunization cards may be obtained from the Immunization Action Coalition at www.immunize.org.

Providing the materials in this packet does not preclude clinic personnel from verbally educating potential vaccinees. Provide all individuals considering vaccination the opportunity to discuss the topics covered in these materials with a trained health care provider.

The materials in this packet may be revised periodically. Each state is responsible for ensuring that all of their participating smallpox vaccination clinics use the most current versions of the materials. All current print materials are available on the CDC's smallpox website at www.cdc.gov/smallpox.

States May Alter and/or Supplement the Materials Only as Follows

As stated previously, CDC requires use of the materials in this packet, without alteration. States, however, may alter or supplement the materials only as follows:

- Some states may wish to supplement the CDC packet with statements on workers compensation coverage, health insurance coverage and/or wage issues. CDC does **not** need to review such materials.
- Some states may wish to include a cover letter when providing the CDC information packet. In general, we recommend that such letters be short given the amount of other materials to be provided to potential vaccinees. Cover letters and other supplemental materials must not contradict information already in the CDC information packet. CDC does not need to review cover letters that merely address logistical issues related to volunteering for the response teams and arrangements for being immunized.
- In particular circumstances, with CDC's concurrence, states may choose to apply further restrictions in availability of smallpox vaccination within their jurisdictions. States may explain these

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restrictions by using supplemental materials, provided they are **approved by CDC**. Specifically, some states have expressed interest in excluding from smallpox vaccination in the early phases of the program individuals who have children less than one year of age in their household. The ACIP has noted that this is not a contraindication to receipt of smallpox vaccine. However, as noted, states may choose to further restrict availability of the smallpox vaccine to certain populations. Materials should not describe such a state restriction as a "contraindication."

- The CDC Patient Medical History and Consent Form must be used. If a state determines that state law requires an additional consent form, CDC needs to review and approve the additional form. Such requests must be accompanied by an explanation of the specific provisions of state law that require an additional consent form.
- CDC does not object to states reformatting the Patient Medical History and Consent Form to ease data entry as long as the content is identical to the original form.
- The CDC Patient Medical History and Consent Form no longer includes fields to collect employer information or a medical screener signature. Some states may wish to continue to collect employer, employer address, and medical screener signatures and may do so without obtaining approval from CDC.

Each state is responsible for ensuring that all of their participating smallpox vaccination clinics use the entire CDC smallpox vaccine information packet and approved state supplements, without alteration.

Submit all proposed supplemental materials to Raymond Strikas, M.D., ras8@cdc.gov, 404-639-8813, and Denise Jackson, at dhj9@cdc.gov, 404-639-8775. CDC will reply to requests for approval within two working days with approval, disapproval with explanation, or note we need more time to review.

For more information, visit www.cdc.gov/smallpox or call the CDC Clinician Information Line at (877) 554-4625 (English)



Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

NOV 10 2003

Dear Colleague:

We are at a crossroads in public health. In 1980, we eradicated smallpox as a naturally occurring disease. Now, this contagious, deadly disease may be brought back as a biological weapon. The most effective tool we have against the disease is the smallpox vaccine, which carries its own risks.

President Bush has initiated a national preparedness program to protect our citizens against smallpox as a biological weapon. Communities have been asked to form smallpox preparedness teams that are ready for a potential smallpox attack on our country. Some of you must now decide whether to participate in this effort and receive the vaccination so that you might protect others. You must weigh your decision carefully.


As you consider participating on a smallpox preparedness team, and before making any decision, please read the materials in the enclosed Smallpox Pre-Vaccination Information Packet. The packet includes the smallpox Vaccination Information Statement (VIS) and a screening worksheet. Please also view the brief video entitled "Decision Point for the Smallpox Vaccine Candidate." These materials are available on the CDC website at www.cdc.gov/smallpox, along with additional information about smallpox and smallpox vaccination.

If you have any questions, please consult your healthcare provider prior to vaccination. Your safety is our highest priority.

We recognize the decision about whether or not to participate in a smallpox preparedness team is difficult. Therefore, we urge you to read, understand, and weigh all the information concerning your personal risks against your ability to help protect those in your community against a potential attack.

On behalf of all of us in public health, we truly thank you for taking the time to make this important decision.

Sincerely,


Julie Louise Gerberding, M.D., M.P.H.
Director

Enclosure

SMALLPOX VACCINE

WHAT YOU NEED TO KNOW

1 WHAT IS SMALLPOX?

Smallpox is a serious disease that can kill up to 3 out of 10 people who get it.

Smallpox can also cause—

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

Smallpox is caused by a virus called "**variola**," which spreads from person to person. Usually, face-to-face contact lasting 3 or more hours is needed to spread smallpox from one person to another. Smallpox can also be spread through direct contact with infected body fluids or objects such as bedding or clothing that have smallpox virus on them.

Smallpox killed millions of people over the centuries. Smallpox vaccination was developed in 1796. As a result, the last outbreak of smallpox in the United States was in 1949. The world's last case of naturally occurring smallpox was in 1977. Routine vaccination of the American public against smallpox ended in 1972.

2 WHAT IS THE SMALLPOX VACCINE?

Smallpox vaccine is made from a living virus called "**vaccinia**." Vaccinia virus is like smallpox virus, but less harmful.

The smallpox vaccine can **NOT** give you smallpox.

The vaccine is not a shot like other vaccines. The needle is pricked into the skin a number of times in a few seconds (usually in the upper arm). The pricking is not deep, but will cause one or two small drops of blood to form. The place on the skin where the vaccine is given is called the "vaccination site."

Getting the vaccine—

- ◆ *before exposure* will protect most people from smallpox (the vaccine is about 95% effective).
- ◆ *up to 3 days after exposure* can prevent the disease or at least make it less severe.
- ◆ *4-7 days after exposure* can still make the disease less severe and decrease the chance of death.

Smallpox vaccine protects people from getting smallpox for 3 to 5 years. Protection from severe illness and death can last 10 years or more.

3 WHY GET VACCINATED NOW?

Smallpox vaccine protects people from smallpox.

Some people should get the vaccine because they work with smallpox or related viruses in laboratories.

Others are being offered the vaccine so they can assist in responding to a smallpox outbreak. Smallpox virus is kept in two approved laboratories in the United States and Russia. There is concern that terrorists may have obtained the smallpox virus and could use it as a weapon. If this happened, many people could become ill and many could die.

The U.S. needs teams of health care providers and others to be vaccinated so they can respond quickly if a smallpox attack happens. These teams will do many things to help control a smallpox outbreak, including quickly vaccinating people who have been exposed to the disease.

4

WHO SHOULD GET SMALLPOX VACCINE AND WHEN?

When There is **NO** Smallpox Outbreak—

You should get the smallpox vaccine if you—

- ◆ Are a lab worker who works with smallpox or viruses like it.
- ◆ Are a member of a smallpox response team.

When There **IS** a Smallpox Outbreak—

You should get the smallpox vaccine if you—

- ◆ Are directly exposed to smallpox virus.

If there is a smallpox outbreak, public health experts will say who else should get the vaccine.

Vaccinated persons may need to get the vaccine again at least every 3-10 years, depending on their risk of exposure to smallpox or related viruses.

5

WHO SHOULD **NOT** GET THE SMALLPOX VACCINE, OR SHOULD WAIT?

When There is **NO** Smallpox Outbreak—

You should **NOT** get the smallpox vaccine if you—

◆ Have Skin Problems

People with skin problems are at risk of developing rashes which can be severe if they get the smallpox vaccine.

- ▶ Anyone who has atopic dermatitis (often called eczema) or had it in the past, should not get the smallpox vaccine.
- ▶ Anyone who has Darier's disease (a skin disease that usually begins in childhood) should not get the smallpox vaccine.
- ▶ Anyone who has a skin problem that has made many breaks in the skin (such as an allergic rash, bad burn, impetigo, psoriasis, pityriasis rosea, poison oak, poison ivy, chickenpox, shingles, herpes, or very bad acne) should not get the vaccine now. They should wait until the skin heals before getting the smallpox vaccine.

◆ Have Immune System Problems

Rarely, when a person with a weakened immune system gets the smallpox vaccine, their vaccination site does not heal. Instead, it spreads to other parts of the body. This reaction can be life-threatening. Anyone with a weakened immune system should **NOT** get the smallpox vaccine, including anyone who:

- ▶ Has HIV/AIDS, primary immune deficiency disorders, humoral (antibody) immunity problems (such as agammaglobulinemia or lack of normal antibodies), or other diseases that affect the immune system.
- ▶ Has lupus or another severe autoimmune disease that weakens the immune system.
- ▶ Has leukemia, lymphoma, or most other cancers.
- ▶ Is taking cancer treatment with radiation or drugs, or has taken such treatment in the past 3 months.
- ▶ Is taking, or has recently taken, drugs that affect the immune system. These include high-dose steroids (for 2 weeks or longer within the past month), some drugs for autoimmune disease, or drugs taken for an organ or bone marrow transplant.

◆ Have Heart Problems

Smallpox vaccination may cause heart inflammation that can be mild to life-threatening. It is not known who is at risk for this problem. As a precaution, anyone who has been told by a doctor that they have a heart condition should **NOT** get the smallpox vaccine, even if they feel well. This includes anyone who has:

- ▶ Known heart disease, such as past heart attack or angina (chest pain caused by lack of blood to the heart).
- ▶ Congestive heart failure
- ▶ Cardiomyopathy (heart muscle becomes enlarged and does not work as well as it should)
- ▶ Stroke or transient ischemic attack (a "mini-stroke" that causes stroke-like symptoms, but no lasting damage)
- ▶ Chest pain or shortness of breath with activity (such as walking up stairs)
- ▶ Other heart conditions that require the care of a doctor

In addition, anyone with **3 or more** of the following risk factors should **NOT** get the smallpox vaccine:

- ▶ Have been told by a doctor that you have high blood pressure.
- ▶ Have been told by a doctor that you have high blood cholesterol.
- ▶ Have been told by a doctor that you have diabetes or high blood sugar.
- ▶ Have a first degree relative (for example, mother, father, sister or brother) who had a heart condition before the age of 50.
- ▶ Smoke cigarettes now

◆ **Are Pregnant or Breastfeeding**

Babies of mothers who have been vaccinated while pregnant or during the month before they become pregnant can get a very rare but serious infection from the vaccine.

- ▶ Do **NOT** get the smallpox vaccine if you are pregnant, think there is a chance you are pregnant, or think you might become pregnant within 4 weeks after vaccination.
- ▶ Sexually active women are encouraged to take a pregnancy test before getting the vaccine. The test should be done the day their vaccination is scheduled. But be aware that even the best tests may not detect early pregnancies (those less than 2 weeks).
- ▶ Take steps to prevent pregnancy during the month before and the month after vaccination:

- ◆ Do not have sex, **or**
- ◆ Use effective birth control **every time** you have sex. Effective birth control methods include male or female sterilization, hormonal methods (such as birth control pills, implants, patches or injections) and intrauterine devices (IUDs). Condoms and the use of spermicide with diaphragms, sponges, or cervical caps are also acceptable methods, although they are less effective. Do **NOT** rely solely on the rhythm or 'natural family' planning method.

- ◆ Do **NOT** get the smallpox vaccine if you are breastfeeding. Follow this advice even if you are pumping and then bottle-feeding breast milk. It is not known if smallpox vaccine virus or antibodies can be passed to babies through breast milk.

◆ **Other Reasons—Do NOT Get the Smallpox Vaccine if You—**

- ▶ Are very allergic to polymyxin B, streptomycin, chlortetracycline, neomycin, or latex.
- ▶ Had a bad reaction the last time you got the smallpox vaccine.
- ▶ Are using steroid drops in your eyes.
- ▶ Are moderately or severely ill the day of your vaccination appointment. Wait until you are better before getting the smallpox vaccine.

◆ **You should NOT get the smallpox vaccine if you live with or have close physical contact with anyone (such as a sex partner) who—**

- ▶ Has any of the skin problems listed above.
- ▶ Has any of the immune system problems listed above.
- ▶ Is pregnant or may become pregnant within 4 weeks of your vaccination.

The smallpox vaccine may pose a similar risk to them.

Smallpox vaccine is not routinely recommended for anyone under 18 years of age or for older people. People age 65 or older who do not have any of the conditions listed above should talk to their health care provider before getting the vaccine.

If There IS a Smallpox Outbreak—

These restrictions may not apply. Public health experts will say who should get the vaccine at that time.

6

WHAT SHOULD YOU EXPECT AFTER VACCINATION?

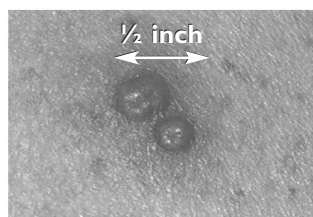
Normal Reactions

Week 1: Three or 4 days after vaccination, a red, itchy bump will form at the “vaccination site”. Most times, this spot is about the size of a dime. It can be larger than 3 inches. The bump becomes a blister. It will fill with pus and then start to drain.

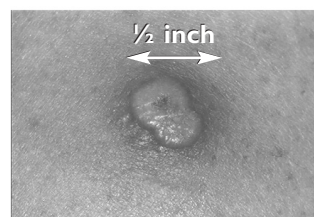
A health care provider should check your vaccination site 6–8 days after you get the vaccine to make sure the vaccination worked and everything is o.k.

Week 2: The blister will dry up and a scab will form.

Week 3: The scab will fall off. It will leave a small scar.



Day 4



Day 7



Day 14



Day 21

The lymph nodes under your arm may swell and be sore. The vaccination site may itch. You may also feel tired, have a mild fever, headache, or muscle aches.

You may not get a blister if the vaccine did not work properly or if you are already immune to smallpox. In this case, you will need to get the vaccine again. If you still do not get a blister after getting the vaccine a second or third time, a health care provider will tell you if you are, or are not, considered immune.

What You Will Need to Do

The virus in the vaccine is alive. It can be spread from the vaccination site to other parts of your body or to other people through close physical contact. This can happen until the scab falls off.

In the past, the vaccine virus was spread from vaccinated people to others about 2 to 6 times out of every 100,000 people vaccinated for the first time (this usually happened between people who lived together).

To Help Prevent Spread of the Virus:

- ◆ **Cover the area** loosely with a gauze bandage held in place with first aid tape. While at work, health care workers should also cover the gauze with a semi-permeable bandage (this type of bandage allows air to flow through but not fluids).
- ◆ Change the bandage often (at least every 3 days).
- ◆ **Try not to touch your vaccination site.**
- ◆ Do not let others touch the site or items that have touched it such as bandages, clothes, sheets, or towels.
- ◆ Always **wash your hands** with soap and water or alcohol-based hand wash if you touch the site or if you touch bandages, clothes, sheets, or towels that have touched the site.
- ◆ Keep the vaccination site dry. If the gauze bandage gets wet, change it right away. Cover your vaccination site with a waterproof bandage while bathing.
- ◆ Don't scratch or put ointment on the vaccination site.
- ◆ Don't touch your eyes, any part of your body, or another person after changing the bandage or touching the vaccination site until you have washed your hands.
- ◆ Wear a shirt that covers the vaccination site and bandage. This helps protect those you have close contact with such as young children or the person you share a bed with.
- ◆ Don't share towels.
- ◆ Do your own laundry. Use a separate laundry hamper for clothes, towels, sheets, and other items that may come into contact with your vaccination site or pus from the site. Machine wash items that have touched the vaccination site in hot water with detergent and/or bleach.
- ◆ Put used bandages in plastic zip bags, then throw them away in the regular trash.
- ◆ After the scab falls off, put it in a plastic zip bag and throw it away.

If you do not feel like you can follow these instructions, do not get vaccinated.

7 WHAT ARE THE RISKS FROM THE SMALLPOX VACCINE?

A vaccine, like any medicine, can cause serious problems. There is a very small risk of smallpox vaccine causing serious harm, or death.

The following information is about known reactions to smallpox vaccine. There may be other unknown side effects.

People who did not get the vaccine can also have the side effects described below if they touch someone's vaccination site or items that have touched the site (like bandages, clothes, sheets, or towels). Following instructions on how to care for the vaccination site (such as covering the site and washing hands) can help prevent spread of the vaccine virus to others.

| MILD TO MODERATE PROBLEMS | HOW OFTEN DID IT HAPPEN IN THE PAST? |
|--|---|
| Feel sick enough to miss work | About 1 out of 10 to 20 people vaccinated |
| Fever of over 100°F | About 1 out of 10 people vaccinated |
| Mild rash that gets better without medicine | About 1 out of 12 people vaccinated |
| Blisters on other parts of the body | About 1 out of 10,000 people vaccinated |
| MODERATE TO SEVERE PROBLEMS CALL OR VISIT A HEALTH CARE PROVIDER | HOW OFTEN DID IT HAPPEN IN THE PAST? |
| Eye infection from touching your eye if you have vaccine virus on your hand. This can lead to a loss of vision in the infected eye. | About 1 out of 45,000 people vaccinated |
| Rash on entire body which usually goes away without problems | About 1 per 15,000 people vaccinated |
| Inflamed heart (can be mild to life-threatening) | About 1 out of 10,000 people vaccinated for the first time |
| SEVERE OR LIFE-THREATENING PROBLEMS GET TO A HEALTH CARE PROVIDER IMMEDIATELY | HOW OFTEN DID IT HAPPEN IN THE PAST? |
| Severe rash on people with eczema or atopic dermatitis, which can lead to scarring or death. | About 1 out of 26,000 people vaccinated |
| Encephalitis (severe brain swelling), which can lead to permanent brain damage or death. | About 1 out of 83,000 people vaccinated |
| Skin and tissue destruction starting at the vaccination site and spreading to the rest of the body, which can lead to scarring or death (usually happens in people with very weakened immune systems). | About 1 out of 667,000 people vaccinated |
| Vaccinia virus infection in unborn child that can lead to premature delivery, skin rash with scarring, stillbirth, or death of the child after delivery | Very rare, less than 50 cases have been reported throughout the world in the last 100 years |

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

The numbers provided above for severe or life-threatening problems are from studies done in the 1960's when the smallpox vaccine was still routinely used in the U.S. The numbers reflect how often the problems occurred in infants, children, and adults.

The numbers provided for all other problems are from recent studies and experiences vaccinating members of response teams and the military.

8 WHAT IF SOMEONE HAS A MODERATE, SEVERE OR LIFE-THREATENING PROBLEM?

Within a Few Minutes to a Few Hours of Getting the Vaccination, Watch For—

- ◆ Trouble breathing, hoarseness or wheezing.
- ◆ Hives, pale skin, weakness, a fast heart beat, or dizziness.

These could be signs that you are having an allergic reaction to the vaccine.

For the Next 3 to 4 Weeks, Keep Watching For—

- ◆ A vaccination site that is not healing.
- ◆ A rash or sore on other parts of your body.
- ◆ An eye infection.
- ◆ A lasting headache or fever.
- ◆ Confusion, seizures, or trouble staying awake.
- ◆ Chest pain, shortness of breath, rapid or unusual heartbeat or unusual fatigue.
- ◆ Any unexpected health problem.

What Should You Do?

If you or a close contact have any of these problems, or if you are concerned about any health problem that you have after vaccination—

- ◆ Call or go to a health care provider right away.
- ◆ Tell the health care provider that you received the smallpox vaccine and when.
- ◆ Ask your doctor or nurse to file a Vaccine Adverse Event Report (VAERS form) and contact the health department. You can also file a report yourself by visiting the VAERS website at www.vaers.org or by calling **1-800-822-7967**.

Treating Serious Problems

There are two drugs that may help people who have certain serious side effects from the vaccine: Vaccinia Immune Globulin (VIG) and cidofovir. These drugs are not licensed for this purpose, and may also cause side effects.

Cost of Treating Serious Problems

In the rare event that you have a serious reaction to the smallpox vaccine, a federal program has been created to help pay for related costs of medical care and lost wages. This program was created to compensate certain people, such as health care workers and emergency responders, injured by the vaccine. It will also cover certain people injured as the direct result of exposure to vaccinia through contact with certain people who received the smallpox vaccine (or with the contacts of such vaccine recipients). The program covers related costs of medical care and lost wages (usually starting after the first five days of missed work) after other available coverage, such as workers' compensation or health insurance, has been used.

The Department of Health and Human Services will make more information about this program available soon, including how to request benefits and/or compensation. For more information contact Paul T. Clark, Director, Smallpox Vaccine Injury Compensation Program, Office of Special Programs, **888-496-0338** or go to www.hrsa.gov/smallpoxinjury.

9 HOW CAN YOU LEARN MORE?

- ◆ Ask your health care provider. They can give you more information, show you the vaccine package insert or suggest other sources of information.
- ◆ Call your local or state health department.
- ◆ Visit the Centers for Disease Control and Prevention (CDC) smallpox website at www.cdc.gov/smallpox
- ◆ Contact the (CDC):
 - ▶ Call **1-888-246-2675** (English)
 - ▶ Call **1-888-246-2857** (Español)
 - ▶ Call **1-866-874-2646** (TTY)

If you decide to get the smallpox vaccine, please **KEEP THIS DOCUMENT** for one month following vaccination.



Pre-Event Screening Worksheet for Smallpox Vaccine

You have received a smallpox Vaccine Information Statement ("VIS") called "Smallpox Vaccine: What You Need to Know." The VIS contains important information about smallpox vaccination. The VIS describes people who should not get the smallpox vaccine or should wait to get the vaccine because of their own health or the health of their "close contacts." ("Close contact" means a person who you live with. It also means a person you have close physical contact with, such as a sex partner or someone you share a bed with. Friends or people you work with are not "close contacts.")

Please read the VIS very carefully and then answer the questions in this worksheet. The VIS and the questions in this worksheet will help you decide if you should or should not get the smallpox vaccine. Answer each question the best you can. **Some questions in this worksheet are very personal.** You should **not** put your name on this worksheet. The worksheet is for you to keep. The staff at the smallpox vaccination clinic will not ask for or collect this sheet. If you wish, you may ask clinic staff questions concerning this sheet.

Ask a health care provider for help if you do not understand a question or if you have any concerns. If you need more information, visit www.cdc.gov/smallpox. You can also call (888) 246-2675 (English), (888) 246-2857 (español), or (866) 874-2646 (TTY). The calls are free.

- If you answer "NO" to **ALL** the questions on this sheet, then you may go to the vaccination clinic to get the vaccine.
- If you answer "YES" to one or more questions, follow the advice that is given.
- **If you don't know, get answers from your health care provider (or your close contact's health care provider) before going to the vaccination clinic.**

Please read the following important information about HIV infection before completing this form.

Up to 300,000 people in the United States may have HIV infection and do not know it. You can have HIV infection and feel fine. If you have HIV infection you can have very bad side effects from the smallpox vaccine. So, before getting the vaccine, it's important to know if you have HIV infection. If you do not know, get an HIV test. Below is a list of things that may place you at higher risk for having HIV infection. **If any of these apply to you, be sure to get tested for HIV before you get the smallpox vaccine.**

You should get tested for HIV if you

- Use needles to inject anything **NOT** prescribed by your doctor
- Were stuck by a needle by accident
- Had sex with someone who has HIV/AIDS or tested positive for HIV/AIDS
- Had sex with a prostitute or someone who takes money or drugs for sex
- Had sex with someone who has ever used needles to inject anything **NOT** prescribed by a doctor
- **For women:** Had sex with a man who has ever had sex with another man
- **For men:** Had sex with another man

Pre-Event Screening Worksheet for Smallpox Vaccine

(continued from previous page)

A. Please answer these questions about your health and the health of your close contacts

| Health Conditions | Do you have this condition? | Does a close contact have this condition? |
|---|--|---|
| Have cancer now, or have been treated for cancer in the past 3 months | <input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated | <input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated |
| Had an organ or bone marrow transplant | <input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated | <input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated |
| Have a disease that affects the immune system like HIV/AIDS, lymphoma, leukemia, or a primary immune deficiency disorder | <input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated | <input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated |
| Have lupus or another severe autoimmune disease that may weaken the immune system | <input type="checkbox"/> YES <input type="checkbox"/> NO ↓ WAIT to get the vaccine until AFTER you check with a doctor | <input type="checkbox"/> YES <input type="checkbox"/> NO ↓ WAIT to get the vaccine until AFTER you check with your contact's doctor |
| Have Darier's disease, a skin disease that usually begins in childhood | <input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated | <input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated |
| Have many breaks in the skin (such as those caused by bad burns, impetigo, psoriasis, pityriasis rosea, herpes, very bad acne, poison ivy, poison oak, chickenpox, shingles, or other rashes such as bad diaper rash and rashes caused by prescription medicines) | <input type="checkbox"/> YES <input type="checkbox"/> NO ↓ WAIT to get the vaccine until AFTER your skin is healed | <input type="checkbox"/> YES <input type="checkbox"/> NO ↓ WAIT to get vaccinated until AFTER your contact's skin is healed |
| Have ever been told by a health care provider you have atopic dermatitis (often called "eczema"), even if the condition is mild, not currently active, or you had it only as a baby or child | <input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated | <input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated |

Some people may not know for sure if they ever had atopic dermatitis (or eczema). Answer these questions to help you **find out if you or a close contact may have had atopic dermatitis or eczema.**

(Version 3)

November 15, 2003

Page 2 of 7

Pre-Event Screening Worksheet for Smallpox Vaccine

(continued from previous page)

1. Do you currently have an **itchy red rash** that comes and goes but usually lasts more than 2 weeks, or did you have such a rash as a baby or child?

YES → You likely have atopic dermatitis (or eczema) and should **NOT** get vaccinated at this time. Please be sure to answer questions 2 and 3.

NO → **SKIP TO question 4**

Don't know → You should discuss any rashes you have with your doctor.

If you can, please write down any information given to you by a doctor regarding this rash:

2. Did the itchy rash affect the creases of your **elbows** or **knees**?

YES → You likely have eczema or atopic dermatitis and should **NOT** get vaccinated at this time

NO

Don't know

3. Did you have **food allergies** as a baby or child?

NO

Don't know

YES → Do you also have **asthma** or **hay fever**?

YES → You likely have eczema or atopic dermatitis and should **NOT** get vaccinated at this time

NO

4. Does a close contact currently have an **itchy red rash** that comes and goes but usually lasts more than two weeks, or did a close contact have this condition as a baby or child?

NO → **SKIP TO Section B**

YES or Don't know → More information is needed about your close contact before you get the smallpox vaccine. **Please answer questions 5-7.** If you do not know the answers to the questions below, please ask the right person to help you answer them. A parent should answer these questions if they apply to a child.

5. Ask your close contact if he or she has an **itchy red rash** that comes and goes but usually lasts more than 2 weeks, or if this person had such a rash as a baby or child?

YES → Your close contact may have eczema or atopic dermatitis. Please gather information so that questions 6 and 7 can be answered. Check with the contact's doctor about the rash.

NO

If you can, please write down any information given by a doctor regarding this rash:

6. Did the itchy rash affect the creases of the **elbows** or **knees**?

Pre-Event Screening Worksheet for Smallpox Vaccine

(continued from previous page)

- YES → Your close contact likely has eczema or atopic dermatitis and you should **NOT** get vaccinated at this time
- NO
- Don't know

7. Did the person with the rash have **food allergies** as a baby or child?

- NO
- Don't know
- YES → Does the person with rash and food allergies also have **asthma** or **hay fever**?
 - YES → Your close contact likely has eczema or atopic dermatitis and you should **NOT** get vaccinated at this time
 - NO
 - Don't know

B. Please answer these questions about treatments or medicines you or your close contact take

(Talk to a health care provider if you are not sure about answers to these questions)

| Treatments or medicines | Are you getting this treatment or taking this medicine? | Is a close contact getting this treatment or taking this medicine? |
|---|---|---|
| Took steroids such as prednisone or related medicine either by mouth or intravenously for 2 weeks or longer in the past month | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated Name and dose of medication: | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated Name and dose of medication: |
| Took medicines in the last 3 months that affect the immune system (such as methotrexate, cyclophosphamide, cyclosporine). If you don't know whether or not your medicine affects your immune system, ask your doctor. | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated Name and dose of medication: | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated Name and dose of medication: |
| Had radiation therapy in the last 3 months | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated |

Pre-Event Screening Worksheet for Smallpox Vaccine

(continued from previous page)

| Treatments or medicines | Are you getting this treatment or taking this medicine? | Is a close contact getting this treatment or taking this medicine? |
|--|---|---|
| Had chemotherapy for cancer in the last 3 months | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated |

C. Please answer these questions about pregnancy. The questions do not apply to women who are post-menopausal (have had no menstrual periods for over a year) or have had a hysterectomy or female sterilization.

| Pregnancy status and pregnancy risk factors | Does this apply to you? (Women only) | Does this apply to a close contact? |
|--|--|---|
| Are pregnant or think you might be pregnant. Sexually active women are encouraged to take a pregnancy test before getting the vaccine. The test should be done the day vaccination is scheduled. But be aware that even the best tests may not detect early pregnancies (those less than 2 weeks). | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated |
| Last menstrual period was not on time and/or was not normal | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated until you check with your doctor to make sure you are not pregnant | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated until your close contact checks with her doctor to make sure she is not pregnant. |
| Had sexual intercourse in the past month and did not always use one or more types of effective birth control, including sterilization (such as vasectomy or tubes tied), birth control pills, implants, patches, injections, IUDs, condoms, and diaphragm with spermicide, cervical cap with spermicide, and contraceptive sponge with spermicide | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated at this time | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated at this time |
| Might have sexual intercourse during the | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO | |

Pre-Event Screening Worksheet for Smallpox Vaccine

(continued from previous page)

| Pregnancy status and pregnancy risk factors | Does this apply to you? (Women only) | Does this apply to a close contact? |
|---|--|--|
| month after vaccination and might not always use an effective form of birth control | ↓ Do not get vaccinated | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated |
| Think menstrual period might be late now | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated until you check with your doctor to make sure you are not pregnant | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated until your contact checks with her doctor to make sure she is not pregnant |

D. Please answer these questions about your own health (these questions do not apply to close contacts)

| Health Conditions | Does this apply to you? |
|---|---|
| Have a heart condition, including any <u>one</u> of the following: <ul style="list-style-type: none"> • a previous heart attack (also called myocardial infarction), angina (chest pain caused by lack of blood flow to the heart), or other coronary artery disease (disease in the vessels that bring blood to the heart) • cardiomyopathy (heart muscle becomes enlarged and doesn't work as it should) • congestive heart failure • 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) • any other heart condition under the care of a doctor | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated (even if you feel well) |
| Have 3 or more of the following: <ul style="list-style-type: none"> • Have been told by a doctor that you have high blood pressure | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO ↓ |

Pre-Event Screening Worksheet for Smallpox Vaccine
(continued from previous page)

| Health Conditions | Does this apply to you? |
|---|--|
| <ul style="list-style-type: none"> • Have been told by a doctor that you have high blood cholesterol • Have been told by a doctor that you have diabetes or high blood sugar • Have a first degree relative (for example mother, father, sister or brother) who had a heart condition before the age of 50 • Smoke cigarettes now | Do not get vaccinated |
| Using steroid drops in your eyes now | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated |
| Have a moderate or serious illness | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO ↓ WAIT to get the vaccine until AFTER you are no longer sick |
| <i>Women only:</i> Are breastfeeding or pumping and then bottle-feeding breast milk | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO ↓ WAIT to get the vaccine until AFTER you stop breastfeeding |
| Have had a serious allergic reaction to polymyxin B, streptomycin, chlortetracycline, neomycin or latex | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated |
| Had a very bad reaction to smallpox vaccine in the past | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated |

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)

**SMALLPOX FACT SHEET (FOR CLOSE CONTACTS OF PEOPLE CONSIDERING VACCINATION)****Someone You Are Close to May Get the Smallpox Vaccine:
What You Should Know and Do**

There are some things you should know and do if someone you have close contact with is thinking about getting the smallpox vaccine. ("Close contact" means anyone living in your household. It also means anyone you have close, physical contact with, like a sex partner or someone you share a bed with. Close contact does not mean friends or co-workers.)

BEFORE Vaccination: What You Should Know

The smallpox vaccine is made from a living virus called "vaccinia." Vaccinia virus is like smallpox virus, but less harmful. The vaccine does not contain the smallpox virus. It can not give you smallpox. The vaccine can protect people from smallpox. For most people, the smallpox vaccine works and is safe.

But, people with certain health conditions are more likely to have serious reactions to the smallpox vaccine. These people should not be vaccinated and they should not be in close contact with someone who has been vaccinated.

BEFORE Vaccination: What You Should Do

Tell your close contact if you have any of the conditions listed below, or even if you have concerns about any of them.

You should NOT be in close contact with someone who has been vaccinated if you:

- Ever had or now have atopic dermatitis, often called "eczema" (even if you had the condition as a baby or child and even if the condition is mild)
- Have many breaks in your skin such as those caused by chickenpox, shingles, bad burns, severe acne, poison oak, poison ivy, herpes, psoriasis, pityriasis rosea, impetigo, or other rashes.
- Have Darier's disease, a skin disease that usually begins in childhood
- Have a weakened immune system for whatever reason (HIV/AIDS, cancer and cancer treatment, lupus or other severe autoimmune diseases, primary immune deficiency disorder, or medicines that affect the immune system like high-dose steroids, some drugs for autoimmune disease, or drugs taken for an organ or bone marrow transplant)
- Are pregnant or might become pregnant within 4 weeks of your close contact's vaccination

Because of the risk to you (or your baby if you are pregnant), you should not be in close contact with someone who has gotten smallpox vaccine if any of these apply to you.

Someone You Are Close to May Get the Smallpox Vaccine: What You Should Know and Do (continued from previous page)

AFTER Vaccination: What You Should Know

There are things you should know if your close contact gets the smallpox vaccine (even if both you and your close contact don't have any health problems).

After vaccination, a bump will form at the place on your close contact's skin where the vaccine was given (called the "vaccination site"). The bump will turn into a blister. It will fill with pus and start to drain. The blister will dry up and form a scab. After about 2 to 3 weeks, the scab will fall off and leave a small scar.

The vaccinia virus in the vaccine (and on your close contact's vaccination site) is a live virus. Until their scab falls off, a person who has been vaccinated can spread vaccinia virus to other people. This can cause problems such as rash (mild to severe), fever, and head and body aches in the other person.

Vaccinia is spread by touching the vaccination site before the scab has fallen off, or by touching items like bandages, clothes, sheets, or towels that have touched the site.

In the past, the vaccine virus was spread from vaccinated people to others about 2 to 6 times out of every 100,000 people vaccinated for the first time. This usually happened between people who lived together.

AFTER Vaccination: What You Should Do

Until your close contact's scab falls off:

- Do not touch your close contact's vaccination site or any items that have touched it (such as bandages, clothes, sheets, towels, or washcloths used by the person who got the vaccine).
- Wash with soap and warm water right away if you accidentally touch the vaccination site or items that were in contact with it. Do not touch your eyes or any part of your body until you have washed your hands.
- If you share a bed with the vaccinated person, be sure that they wear a gauze bandage held in place with first aid tape. To be extra careful, the person who got the vaccine should wear a shirt or pajamas that cover the bandage. If they do not, you may choose to sleep in another bed.
- Don't share towels or clothing. Keep clothes, towels, sheets, or other items used by the vaccinated person separate. He or she should machine wash items that have touched the vaccination site using hot water with detergent and/or bleach.
- Remind the person who got the vaccine to follow the vaccination site care and hand washing instructions they have been given. The vaccination site often becomes itchy, which may lead to scratching, rubbing, or touching of the site. If their hand has vaccinia virus on it and they touch you, you can be infected.

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)

SMALLPOX VACCINATION PATIENT MEDICAL HISTORY AND CONSENT FORM

For Clinic Use Only:

Initial Vaccination:
 Revaccination: (Initial PVN _____)
 Date: _____
mm dd yyyy

Place Patient Vaccination
 Number (PVN) sticker here

PATIENT MUST COMPLETE SECTIONS A, B, C, D, E and F. Please use pen and print.

SECTION A GENERAL PATIENT INFORMATION

Title: _____ First Name: _____ Middle Name: _____
(Mr., Ms., Mrs., Dr., etc.)

Last Name: _____ Suffix: _____
(Jr., Sr., MD., etc.)

Social Security Number (optional): _____

†Date of Birth (year is required): _____ Gender: Male Female
mm dd yyyy

Street Address: _____ Apt. #: _____
 City: _____ State: _____
 Zip code: _____ County: _____

Your Contact Information:

Home Phone: (____) _____ - _____ Work: (____) _____ - _____ ext. _____
 Cell Phone: (____) _____ - _____ Fax: (____) _____ - _____
 Beeper/Pager: (____) _____ - _____ Beeper/Pager PIN #: _____
 E-mail Address: _____

Occupation: _____

Ethnicity/Race (optional, you do not have to provide this information. If you choose to provide this information, you may select more than one category):

Hispanic or Latino Ethnicity Asian Black or African American
 Native Hawaiian or other Pacific Islander American Indian or Alaska Native White

†Did you serve in the military before 1984? Yes No

SECTION B PATIENT VACCINATION HISTORY

How many times have you already received smallpox vaccination? Do NOT count smallpox vaccinations you received since January 2003 as part of the National Smallpox Vaccination Program (NSVP)

0 1 2 More than 2 Don't know

Enter the year of the **most recent** vaccination prior to the NSVP if known: _____

†Please indicate source of date: Document (e.g., vaccination card) self-recall (from memory)

If year of your **most recent** vaccination prior to the NSVP is unknown: (check one)

I was vaccinated in childhood but can't recall the date
 I was vaccinated in adulthood but can't recall the date

Have you been told (for instance, by a doctor or a parent) that your vaccination was successful?
 Yes No Don't Know

Do you have a vaccination scar? Yes No Don't Know

Did you have any bad reaction(s) to the vaccine? Yes No Don't know

If yes, you should not get the vaccine at this time if the reaction(s) was serious.
 Please tell us about the reaction(s) _____

DEPARTMENT OF HEALTH AND HUMAN SERVICES
 CENTERS FOR DISEASE CONTROL AND PREVENTION



Date: / /
 mm dd yyyy

Patient Name: _____ PVN: _____

SECTION C PATIENT CONTACT AFTER VACCINATION

During the month following vaccination, you may be contacted for routine follow-up.
May we also contact you in the future about participating in a survey? Yes No

SECTION D REFERRING ORGANIZATION

Please provide the following information about the organization that referred you for vaccination.

Name: _____

Street Address: _____

City: _____ State: _____ Zip code: _____

County: _____ Phone: (_____) _____ - _____

SECTION E PATIENT MEDICAL HISTORY

Have you received chickenpox (varicella) vaccination in the last month? Yes No
If yes, you should not get the smallpox vaccine at this time.

Are you currently taking medication? Yes No

If yes, please list medications (also see questions 3, 4, and 17 below):

Are you sick today? Yes No

If yes, please describe your illness, you may need to wait to get the vaccine

Do any of the following apply to YOU? Yes No

Weakened Immune System

1. Do you have any conditions that weaken the immune system such as HIV/AIDS; leukemia, lymphoma, or most other cancers; organ transplant; or primary immune deficiency disorders?
2. Do you have a severe autoimmune disease such as lupus that may weaken the immune system?
3. Are you now taking, or have you recently taken, drugs that can weaken the immune system like steroids (e.g. prednisone), some medicines for autoimmune disease, or medicines taken after an organ transplant?
4. Are you now taking cancer treatment with drugs or radiation or have you taken such treatment in the past 3 months?

Skin Problems

5. Do you now have, or have you ever had atopic dermatitis, often called eczema (even as a baby or child and even if the condition is mild)?
6. Do you now have other skin problems that have made many breaks in your skin such as a rash, severe burn, impetigo, chickenpox, shingles, herpes, psoriasis, or severe acne?
7. Do you have Darier's disease (a skin problem that usually begins in childhood)?

Heart Problems

8. Have you ever been diagnosed by a doctor as having a heart condition with or without symptoms such as previous myocardial infarction (heart attack), angina (chest pain caused by lack of blood flow to the heart), congestive heart failure, or cardiomyopathy?
9. Have you ever had a stroke or transient ischemic attack (a "mini-stroke" that produces stroke-like symptoms but no lasting damage)?
10. Do you have chest pain or shortness of breath when you exert yourself (such as when you walk up stairs)?
11. Do you have any other heart condition for which you are under the care of a doctor?
12. Do you have three or more of the following risk factors?
 - a. You have been told by a doctor that you have high blood pressure
 - b. You have been told by a doctor that you have high blood cholesterol.
 - c. You have been told by a doctor that you have diabetes or high blood sugar.
 - d. You have a first degree relative (for example mother, father, brother, or sister) who had a heart condition before the age of 50.
 - e. You smoke cigarettes now.

Date: / /
mm dd yyyy

Patient Name: _____ PVN: _____

SECTION E PATIENT MEDICAL HISTORY *continued*

Pregnant or Breastfeeding

- 13. Are you pregnant, might be pregnant, or might become pregnant in the next month?
- 14. In the past month, have you had any sex without using effective birth control or do you think you will have sex without using effective birth control during the month after vaccination?
- 15. Are you currently breastfeeding or pumping and then bottle-feeding breast milk?

Other

- 16. Have you ever had a life-threatening allergic reaction to smallpox vaccine, latex or the antibiotics polymixin B, streptomycin, chlortetracycline, or neomycin?
- 17. Are you now being treated with steroid eye drops?

**IF YOU ANSWERED YES TO ANY OF THE QUESTIONS ABOVE,
YOU SHOULD NOT GET THE SMALLPOX VACCINE AT THIS TIME.**

If you answered NO, please continue with the following questions about your close contacts.

Do any of the following apply to your CLOSE CONTACTS? Yes No

(A close contact is someone you live with or have close physical contact with, such as a sex partner. Close contacts do not include friends or co-workers.)

Weakened Immune System

- 1. Do any of your close contacts have conditions that weaken the immune system such as HIV/AIDS, leukemia, lymphoma, or most other cancers; organ transplant; or primary immune deficiency disorders?
- 2. Do any of your close contacts have a severe autoimmune disease such as lupus that may weaken the immune system?
- 3. Are any of your close contacts now taking, or have they recently taken, drugs that can weaken the immune system like steroids (e.g. prednisone), some medicines for autoimmune disease, or medicines taken after an organ transplant?
- 4. Are any of your close contacts taking cancer treatment with drugs or radiation or have they taken such treatment in the past 3 months?

Skin Problems

- 5. Do any of your close contacts now have, or have they ever had atopic dermatitis, often called eczema (even as a baby or child and even if the condition is mild)?
- 6. Do any of your close contacts now have other skin problems that have made many breaks in their skin such as a rash, severe burn, impetigo, chickenpox, shingles, herpes, psoriasis, severe diaper rash, or severe acne?
- 7. Do any of your close contacts have Darier's disease (a skin problem that usually begins in childhood)?

Pregnancy

- 8. Are any of your close contacts pregnant, might be pregnant, or might become pregnant in the next month?

**IF YOU ANSWERED YES TO ANY OF THE QUESTIONS ABOVE,
YOU SHOULD NOT GET THE SMALLPOX VACCINE AT THIS TIME.**

Screener comments/Notes for clarification (for clinic use only) _____

Date: _____
mm dd yyyy

Patient Name: _____ PVN: _____

SECTION F SIGNED CONSENT (TO BE KEPT BY THE VACCINATION CLINIC)

I have:

- received, read and understand the Smallpox Pre-Vaccination Information Package, including the Vaccine Information Statement (VIS) and the pre-event screening worksheet;
- considered my own health status as well as the health status of my close contacts;
- had the opportunity to discuss my medical concerns with my health care provider or a health care provider at the vaccination clinic;
- had the opportunity to obtain a referral to seek confidential laboratory testing for medical conditions that may increase my risk for adverse reactions from the vaccine;
- responded to the questions above to the best of my ability.

I understand that getting the vaccine is my choice. I agree to get the smallpox vaccine.

Patient signature

Date

Privacy Act Statement

The information requested on this form, including the Social Security Number (SSN), is collected under the authority of Section 311 of the Public Health Service Act (42 U.S.C. 243), the NCVIA (42 U.S.C. 300aa-2(a)), and Section 304 of the Homeland Security Act of 2002 (Pub. L. No. 107-296). The information will be used in the analysis and follow-up of significant events associated with smallpox vaccination and to assure availability of smallpox response teams. The SSN is being collected for identity verification purposes. Furnishing the requested information, including SSN, is voluntary; however, with more complete information, public health objectives, such as adequate monitoring and follow-up of potential adverse events, are more readily achievable. Individuals who do not provide all of the requested information (except items marked as optional) will not be eligible to receive the smallpox vaccine. Identifiable information may be shared by the Centers for Disease Control and Prevention with authorized U.S. Department of Health & Human Services' personnel and public health or cooperating medical authorities.

Date: mm dd yyyy

Patient Name: PVN:

SECTION G CURRENT VACCINATION INFORMATION (CLINIC STAFF WILL FILL OUT THIS SECTION)

Vaccination clinic and vaccine batch information do not need to be filled out if a pre-printed, pre-populated PVS patient medical history and consent form attachment is used.

Vaccination Clinic Information

Name: _____
Street Address: _____
City: _____ State: _____ Zip code: _____
County: _____ Phone: (____)____ - _____ Fax: (____)____ - _____

Disposition

Referred for Vaccination Deferred for medical reasons Vaccination refused

† Was a smallpox vaccination scar seen by clinic staff? Yes No

† Vaccinee status? Primary vaccinee Revaccinee

Vaccination Administration Information

Date of Vaccination: mm dd yyyy Arm vaccinated: Left Right Other: _____

Vaccine Administered by: _____
Please print first name, last name, and professional suffix (MD, RN, etc.)

Vaccine Batch Information

| | |
|---------------------------|---------------------------|
| Vaccine Type: | Batch #: |
| Program: | External #: |
| Dilution Strength: | Batch Date: |
| Diluent Lot #: | Vaccine Lot #: |
| Diluent Lot Manufacturer: | Vaccine Lot Manufacturer: |

Take Evaluation and Response

Name of the organization/clinic where take will be evaluated: _____
Street Address: _____
City: _____ State: _____ Zip code: _____
County: _____ Phone: (____)____ - _____
Take response evaluation performed by: _____

Please print first name, last name, and professional suffix (MD, RN, etc.)

Date of Evaluation (should be 6-8 days after vaccination): mm dd yyyy

Take Response (check only one box)

Major (usually successful vaccination is characterized by a pustular lesion or an area of definite induration or congestion surrounding a central lesion, which might be a scab or an ulcer; go to the CDC website listed below for more information)

Equivocal (all other responses)

Not available, reason: _____
(e.g., cannot be contacted, died, hospitalized, refused, other)

Is the vaccinee considered immune for response team work?

Yes (the vaccinee had a Major response or was a revaccinee and had two Equivocal responses)

No

Additional comments: _____

† To determine vaccinee's status, see marked *italicized* items in sections A, B, and G. For more information on determining vaccination status or assessing vaccination responses, go to www.bt.cdc.gov/agent/smallpox/vaccination/statusprocedure.asp

Adverse events should be reported to VAERS at www.vaers.org or 1-800-822-7967





**Temporary Proof of Vaccination and Site Check Reminder Sheet
(To be Completed by Clinic Staff and Kept by the Vaccinee)**

IMPORTANT: KEEP THIS FORM. BRING IT WITH YOU TO YOUR VACCINATION SITE CHECK.

Please bring this sheet with you to your vaccination site check appointment and keep it for the next 4 weeks. This sheet contains the phone number you should call if you think you are having a bad reaction to the vaccine. This sheet is also your proof of vaccination until you come back to the clinic for your vaccination site check. On that date, you will get your permanent immunization card.

TEMPORARY PROOF OF SMALLPOX VACCINATION:

Name: _____ Date vaccinated: ____/____/____
mm/dd/yyyy

PVN: _____ Clinic: _____

Clinic Telephone No.: (_____)_____-_____ Arm Vaccinated: Left Right

APPOINTMENT FOR REQUIRED VACCINATION SITE CHECK:

You will need to get your vaccination site checked on the date below to make sure the vaccination worked.

Date of Appointment: ____/____/____ Time: _____
mm/dd/yyyy

Clinic Name: _____

Street Address _____

City _____ State _____ Zip _____

Clinic Telephone No.: (_____)_____-_____

IF YOU THINK YOU ARE HAVING A BAD REACTION TO THE VACCINE:

Call: _____, call your health care provider, or visit an emergency room.

IMPORTANT: DO NOT DISCARD THIS FORM. BRING IT WITH YOU WHEN YOU RETURN FOR YOUR VACCINATION SITE CHECK.

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)