



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 Package.
- 2. Smallpox Vaccine Information Statement (VIS)** – This document, entitled "Smallpox Vaccine: What You Need to Know," contains basic information about smallpox disease, the benefits and risks of smallpox vaccine, who should not get the vaccine, what to do if a reaction occurs after vaccination, and where to get more information. The supplemental fact sheets listed below provide additional information.
 - a. VIS Supplement A: Reactions After Smallpox Vaccination** – informs readers about expected normal reactions following vaccination, as well as serious and life-threatening reactions.
 - b. VIS Supplement B: Vaccination Site Appearance and Care** – informs readers about the appearance and progression of a successful vaccination and the steps necessary to properly care for the vaccination site.
 - c. VIS Supplement C: Skin Conditions that Mean You Should Not Get Smallpox Vaccine** – informs readers about skin conditions that make a person more likely to experience rare and serious reactions.
 - d. VIS Supplement D: A Weakened Immune System Means that You Should Not Get Smallpox Vaccine** – informs readers about immune system problems that make a person more likely to experience rare and serious reactions.
 - e. VIS Supplement E: Pregnancy Means You Should Not Get the Smallpox Vaccine** – informs readers about the risks of vaccination during pregnancy and the risks of breastfeeding after vaccination.
- 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 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. Fact Sheet: Investigational Vaccinia Immune Globulin (VIG) Information** – Vaccinia Immune Globulin (VIG) is an investigational new drug that may help people who have certain serious reactions to the smallpox vaccine. This sheet contains basic information about VIG, including possible side effects.

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- 6. Fact Sheet: Investigational Vistide® (Cidofovir) Information** – Vistide (cidofovir), is a drug licensed to treat serious eye infections in HIV-infected people. The drug may help people who have certain serious reactions to the smallpox vaccine, but it has not been licensed for this purpose. This sheet contains basic information about cidofovir, including possible side effects.
- 7. Smallpox Vaccine: Decision Point for the Smallpox Vaccine Candidate** – an 11-minute video intended as an overview for use at vaccination clinic sites to supplement the written materials listed above.
- 8. 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.
- 9. Post-Vaccination and Follow-Up Information Sheet** – This form serves as temporary proof of vaccination, contains follow-up appointment information, and instructs vaccine recipients on what to do 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, the federal government will 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.**

- **Provide items 1, 2 (including VIS supplements A-E), 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 1-6 (including VIS supplements A-E)** 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 7**) **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 8**) 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 Post-Vaccination and Follow-Up Sheet (**item 9**). Clinic sites should insert local or state telephone numbers for adverse event reporting.

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- 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.

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)



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

JAN 16 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, a vaccine not without 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 smallpox attack on this country. Some of you must now decide whether you will participate in this effort and receive the vaccination so that you might protect others. Your decision must be weighed carefully.

As you consider your participation on a smallpox preparedness team, please read the materials in the enclosed Smallpox Pre-Vaccination Information Package before making your decision. The Vaccine Information Statement (VIS) and supplemental fact sheets and forms are included in this package. A list of materials follows:

1. Vaccine Information Statement
2. Smallpox Vaccine Information Statement Supplement A: Reactions after Vaccination
3. Smallpox Vaccine Information Statement Supplement B: Vaccination Site Appearance and Care
4. Smallpox Vaccine Information Statement Supplement C: Skin Conditions That Mean You Should NOT Get Smallpox Vaccine
5. Smallpox Vaccine Information Statement Supplement D: A Weakened Immune System Means You Should NOT Get Smallpox Vaccine
6. Smallpox Vaccine Information Statement Supplement E: Pregnancy and Breastfeeding Mean You Should NOT Get Smallpox Vaccine
7. Pre-Event Smallpox Vaccination Screening Worksheet

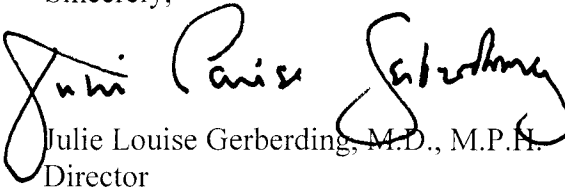
If you have any doubts, you may discuss these issues with your healthcare provider prior to vaccination. Your safety is our highest priority.

We recognize the decision about whether or not to participate in a smallpox preparedness team is difficult. 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. We want you to err on the side of caution and not put you or your loved ones at risk of a serious adverse reaction.

Page 2 - Dear Colleague

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

Sincerely,

A handwritten signature in black ink, reading "Julie Louise Gerberding". The signature is written in a cursive style with a large initial "J" and "L".

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 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

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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.

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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.

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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.

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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.

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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

**SMALLPOX VACCINE INFORMATION STATEMENT (VIS) SUPPLEMENT A****Reactions After Vaccination**

The smallpox vaccine is made from a live virus related to smallpox called vaccinia (not smallpox virus). The vaccine stimulates the immune system to react against the vaccinia virus, and develop immunity to it. Immunity to vaccinia also provides immunity to smallpox. For most people, live virus vaccines are safe and effective.

After smallpox vaccination, most people experience normal, typically mild reactions to the vaccine, which indicate that it is beginning to work. Some people may experience more severe reactions that may require medical attention. Consult the "Smallpox Vaccine Information Statement" (VIS), or relevant supplemental fact sheets for information on people who should not be vaccinated at this time.

Following are listings of what you may expect, and conditions that you should be watchful for:

Normal, Typically Mild Reactions

These reactions usually go away without treatment. They can start right away, or they may not start until a week or more after vaccination:

- The arm receiving the vaccination may be sore and red where the vaccine was given.
- The glands in the armpits may become large and sore.
- The vaccinated person may run a low fever.
- The vaccinated person may have other symptoms like fatigue, headache, or muscle aches.
- One out of 3 people may feel bad enough to miss work, school, or recreational activity or have trouble sleeping.
- The vaccination site may start itching after a few days, this could last until the scab falls off.

Other Things to Expect with Normal Reactions

A recent study found:

- The average size of the pustule (pus-filled blister) at the vaccination site was half an inch.
- The average size of the redness and/or swelling at the vaccination site was 2/3 of an inch.
- Up to 15% of people vaccinated had redness and/or swelling larger than 3 inches, sometimes involving the whole arm. This is usually seen around 7 to 10 days after vaccination.
- Up to 47% of people vaccinated reported pain at the vaccination site, but most said it did not keep them from normal activities.
- About 10% had a fever of 100°F or more. (This can be treated with ibuprofen or acetaminophen.)
- An allergic rash sometimes occurred where the first aid adhesive tape holding the gauze bandage in place touched the vaccine recipient's skin.

If you are concerned about normal reactions:

While these reactions usually go away on their own, if you are concerned about reactions of this type, call the phone number provided on the "Post-Vaccination and Follow-Up Information Sheet" given to you at the time of your vaccination, or call your health care provider.

VIS SUPPLEMENT A: Reactions after Vaccination

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Symptoms That May Mean You Require Medical Attention

Some people may experience more severe reactions that may require medical attention. You should be aware of symptoms that might indicate you are experiencing such a reaction.

Be watchful for the following symptoms:

- Your vaccine site doesn't look like it is healing normally.
- You develop a rash or sore on other parts of your body.
- You develop a persistent headache (lasting more than 24 hours) or high fever, confusion or seizures.
- You have difficulty staying awake.
- You have difficulty breathing, hoarseness or wheezing.
- You develop hives, paleness, weakness, a fast heartbeat or dizziness.
- You develop an eye infection.
- You develop some other atypical, unexpected problem.

If any of the above occur, call the phone number provided on the "Post-Vaccination and Follow-Up Information Sheet" given to you at the time of your vaccination, or call your health care provider.

Serious Reactions That Should Be Evaluated

In the past, about 1,000 people for every 1 million people vaccinated for the first time had reactions that, while not life-threatening, were serious. These reactions may require medical attention:

- A vaccinia rash or outbreak of sores limited to one area (inadvertent inoculation). This is an accidental spreading of the vaccinia virus caused by touching the vaccination site and then touching another part of the body or another person before washing of hands. It usually occurs on the genitals or face, and can include the eyes, where it can damage sight or lead to blindness. Washing hands with soap and water after touching the vaccine site will help prevent this. **Note: If the eyes are affected, seek immediate attention.**
- A widespread vaccinia rash (generalized vaccinia). The virus spreads from the vaccination site through the blood. Sores break out on parts of the body away from the vaccination site.
- An allergic rash in response to the vaccine (erythema multiforme). This can take various forms such as red spots, bumps, or hives.
- Red streaks coming out from the vaccination site are most likely a normal reaction, but could be an infection and should be checked.

Life-Threatening Reactions That Need Immediate Attention

Rarely, people have had very bad reactions to the vaccine. In the past, between 14 and 52 people per 1 million people vaccinated for the first time had potentially life-threatening reactions, and 1 or 2 died.

These reactions require **immediate** medical attention:

- Serious skin rashes (eczema vaccinatum). This is caused by widespread infection of the skin in people with skin conditions such as eczema or atopic dermatitis and can lead to scarring or death.
- Ongoing infection of skin at the vaccination site with tissue destruction (progressive vaccinia or vaccinia necrosum) that can lead to scarring or death.
- Inflammation of the brain (postvaccinal encephalitis) that can lead to disability or death.

VIS SUPPLEMENT A: Reactions after Vaccination

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If you believe you are having one of the reactions above:

Call the phone number provided on the "Post-Vaccination and Follow-Up Information Sheet" given to you at the time of your vaccination, call your health care provider, or visit an emergency room.

Treatment for Serious or Life-threatening Reactions

Two treatments may help people who have certain serious reactions to the vaccine: Vaccinia Immune Globulin (VIG) and cidofovir. Neither drug is currently licensed for this purpose, and may have side effects of their own. More information on each will be available at the clinic facility or can be found at the website listed below.

Unsuccessful Vaccination

Around 3% of people may have no reaction from the vaccine. This could mean that vaccination was not successful and you are not protected. In this case, you would need to be vaccinated again.

***Note:** Adverse events in the U.S. today may be higher than in the past because there may be more people at risk from immune suppression and eczema or atopic dermatitis. The outcome associated with adverse events may be less severe because of advances in medical care. Rates may be lower for persons previously 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)



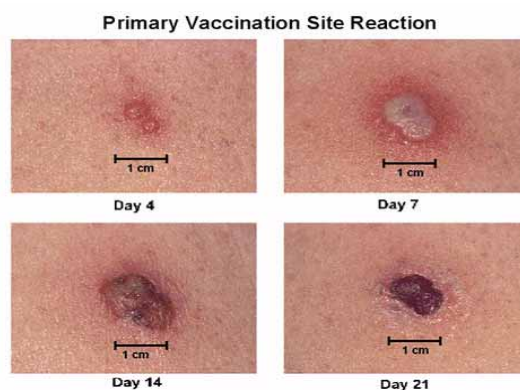
SMALLPOX VACCINE INFORMATION STATEMENT (VIS) SUPPLEMENT B

Vaccination Site Appearance and Care

Appearance

If the vaccination is successful, a red and itchy bump develops at the site of vaccination in 3 or 4 days. In the first week, the bump becomes a blister, fills with pus, and begins to drain. During the second week, the blister begins to dry up and a scab forms. The scab falls off in the third week, leaving a small scar. People vaccinated for the first time may have a stronger reaction than those who are being revaccinated.

The following pictures show the usual progression of the vaccination site:



Major (primary) reaction – Expected site reaction and progression over the three weeks following first-time smallpox vaccination, or following revaccination after a prolonged period. Source: CDC.

Vaccination Site Evaluation

About 7 days after vaccination, you will need to keep an appointment for a vaccination site exam so that someone can evaluate your vaccination site to determine whether the vaccination was successful. The details of this appointment are on the “Post-Vaccination and Follow-Up Sheet” given to you at vaccination.

Look-out for:

If your vaccination site doesn’t look like it is healing normally, or if you develop a rash or sore on other parts of your body, an eye infection, a persistent headache (lasting more than 24 hours) or high fever, confusion, seizures, difficulty staying awake, difficulty breathing, wheezing, hoarseness, hives, paleness, weakness, a fast heartbeat, dizziness or some other unexpected problem, call the phone number provided on the “Post-Vaccination and Follow-Up Information Sheet” or call your health care provider.

Site Care

There will be **vaccinia virus** at the site of your vaccination until the scab that forms after vaccination falls off on its own, between 2 and 3 weeks after vaccination. During this time, vaccinia can be spread to other parts of the body or to other individuals through direct contact (touching the vaccination site or a bandage or clothing contaminated with virus and then touching another part of your body or someone else before hand washing). You should avoid the spread of virus and keep the vaccination site clean and dry. Follow the instructions on the next page carefully.

VIS SUPPLEMENT B: Vaccination Site Appearance and Care

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Site Care Instructions

Follow these instructions until the scab that forms at the vaccination site has fallen off on its own.

WHAT YOU SHOULD DO:

- **When working in a health care setting, cover the vaccination site loosely with gauze, using first aid adhesive tape to keep it in place. Then cover the gauze with a semipermeable (or semioclusive) dressing. Change the bandage at least every 3-5 days in order to prevent build-up of fluids and irritation of the vaccination site. Also wear a shirt that covers the vaccination site** as an additional barrier to spread of vaccinia. (A "semipermeable dressing" is one that does not allow for the passage of fluids but allows for the passage of air.)
- **When not at work in a health care setting, you need only wear the gauze bandage secured by first aid adhesive tape** over the vaccination site. Change the gauze bandage frequently (every 1-3 days). As an **added precaution** against spread of transmission, **wear a shirt** that covers the vaccination site as well. This is particularly important in situations of close physical contact such as occurs in the household.
- **Wash hands with soap and warm water** or with alcohol-based hand rubs such as gels or foams after direct contact with vaccine, the vaccination site, or anything that might be contaminated with live virus, including bandages, clothing, towels or sheets that came in contact with the vaccination site. This is vital in order to remove any virus from your hands and prevent contact spread.
- **Keep the vaccination site dry.** Cover the vaccination site with a waterproof bandage when you bathe. Remember to change back to the loose gauze dressing after bathing. If the gauze covering the vaccination site gets wet, change it.
- **Put the contaminated bandages in a sealed plastic bag and throw them away** in the trash.
- Keep a **separate laundry hamper** for clothing, towels, bedding or other items that may have come in direct contact with the vaccination site or drainage from the site.
- **Wash clothing or any other material that comes in contact with the vaccination site** using hot water with detergent and/or bleach. **Wash hands afterwards.**
- When the scab falls off, **throw it away in a sealed plastic bag** (remember to wash your hands afterwards).

WHAT YOU SHOULD NOT DO:

- **Don't use a bandage that blocks all air from the vaccination site.** This may cause the skin at the vaccination site to soften and wear away. Use loose gauze secured with first aid adhesive tape to cover the site and then cover this with a semipermeable dressing and shirt when at work in a health care setting.
- **Don't put salves or ointments on the vaccination site.**
- **Don't scratch or pick at the scab.** The vaccination site can become very itchy but you should not scratch it.

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 VACCINE INFORMATION STATEMENT (VIS) SUPPLEMENT C****Skin Conditions That Mean You Should Not Get Smallpox Vaccine**

The smallpox vaccine is made from a live virus related to smallpox called vaccinia (not smallpox virus). The vaccine stimulates the immune system to react against the vaccinia virus, and develop immunity to it. Immunity to vaccinia also provides immunity to smallpox. For most people, live virus vaccines are safe and effective. However, people with certain skin conditions are more likely to have rare and serious reactions to the smallpox vaccine, including bad skin rashes (eczema vaccinatum). This results when virus from the vaccine site gets into broken skin and causes a rash in that area. While most people recover from this rash with treatment, it can be quite severe, sometimes leading to scarring or even death.

SKIN CONDITIONS THAT MEAN YOU SHOULD NOT BE VACCINATED:

- Individuals who have ever been diagnosed with **eczema or atopic dermatitis**, (conditions involving repeated episodes of red, itchy or inflamed skin) even if the condition is mild, not presently active, or if you had it only as a child, **should not get the vaccine.**
- Individuals with **Darier's disease** should not get the vaccine.
- Individuals in **close contact** with someone who has ever been diagnosed with **eczema or atopic dermatitis**, even if the condition is mild, not presently active, or if they had it only as a child, **should not get the 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 sexual partner.)

SKIN CONDITIONS THAT MEAN YOU SHOULD WAIT BEFORE BEING VACCINATED:

- Individuals with **breaks in their skin should not be vaccinated until the skin is fully healed.** Below are examples of skin conditions that can result in breaks in the skin.
- Individuals in **close physical contact with someone else who has breaks in their skin should not be vaccinated until the skin is fully healed.**

Examples of conditions that can result in breaks in the skin include:

- Impetigo (a skin infection)
- Varicella (chickenpox or shingles)
- Pityriasis rosea
- Acute contact dermatitis (e.g. poison oak or ivy)
- Recent significant burns (> about 1 inch x 1 inch) where skin has not completely healed
- Other conditions that cause significant rash or breaks in the skin, including moderate or extensive psoriasis, epidermolysis bullosa, severe acne (face or body) and pemphigus vulgaris.

VIS SUPPLEMENT C: Skin Conditions that Mean You Should NOT Get Smallpox Vaccine

(continued from previous page)

What are eczema and atopic dermatitis?

The word **eczema** describes certain kinds of inflamed skin. Early eczema can be red, blistering, or oozing areas of skin. Later on, eczema can be scaly, brownish, or thickened. Almost always, eczema itches. There are several different types of eczema. A special type of eczema called atopic dermatitis or atopic eczema has the greatest risk for severe rashes after smallpox vaccination.

Atopic dermatitis is a chronic disease that affects the skin. "Dermatitis" means inflammation of the skin. "Atopic" refers to a group of diseases that run in families and often occur together (including hay fever and asthma). In atopic dermatitis, the skin becomes extremely itchy and inflamed, causing redness, swelling, cracking, weeping, crusting and scaling. This often affects creases in the elbows or knees. Atopic dermatitis most often affects infants and young children, but it can continue into adulthood or appear later in life. In most cases, there are times when the disease is worse, called exacerbations or flares, followed by periods when the skin improves or clears up entirely, called remissions. Many children with atopic dermatitis will completely recover from this skin disease when they get older, although their skin often remains dry and easily irritated. Environmental factors can bring on symptoms of atopic dermatitis at any time in someone who has inherited the atopic disease trait.

Although it is difficult to know exactly how many people are affected by atopic dermatitis, an estimated 10% of infants and young children experience symptoms of the disease. Roughly 60% of these children continue to have one or more symptoms of atopic dermatitis into adulthood. This means that more than 15 million people in the United States have symptoms of the disease. None of these people should be vaccinated or be in close contact with someone who has been vaccinated because of the potential risk posed by exposure to the live virus in the smallpox vaccine.

What if there is an outbreak of smallpox?

If there is a smallpox outbreak, recommendations on who should get vaccinated will change. Anyone who is directly exposed to smallpox should get vaccinated because the disease poses greater risk than the vaccine. Public health authorities will recommend who should be vaccinated at that time.

How can I learn more?

- Talk to your health care provider if you have any questions or concerns about skin conditions.
- For more information on eczema and atopic dermatitis, visit <http://www.niams.nih.gov/hi/topics/dermatitis/> and <http://www.aad.org/pamphlets/eczema.html>

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 VACCINE INFORMATION STATEMENT (VIS) SUPPLEMENT D****A Weakened Immune System Means You Should Not Get Smallpox Vaccine**

The smallpox vaccine is made from a live virus related to smallpox called vaccinia (not smallpox virus). The vaccine stimulates the immune system to react against the vaccinia virus, and develop immunity to it. Immunity to vaccinia also provides immunity to smallpox. For most people, live virus vaccines are safe and effective. However, people with immune system problems usually are advised to avoid live virus vaccines because their immune systems may not be able to stop the growth of the virus in their bodies. In the case of the smallpox vaccine, while the risk for severe complications for someone with a weakened immune system is unknown, there have been cases of serious reactions to the vaccine. Someone with a weakened immune system might develop a widespread, severe, vaccinia rash (generalized vaccinia), or ongoing severe skin destruction at the vaccination site (progressive vaccinia/vaccinia necrosum).

- Individuals with **suppressed immune systems should not get the smallpox vaccine.**
- Individuals who are **undergoing, or have recently undergone, medical treatment that can weaken their immune system should not get the smallpox vaccine.**
- Individuals **in close physical contact with someone who falls into these categories should not get smallpox vaccine** because of the risk it poses to that close contact. Close contacts include anyone living in your household or anyone you have close physical contact with such as a sex partner.

What are some illnesses that can weaken the immune system?

- HIV/AIDS
- Cancer
- Leukemia
- Lymphoma
- Multiple myeloma
- Primary Immune Deficiency disorders (such as Common Variable Immune Deficiency)
- Humoral (antibody) immunity problems (such as agammaglobulinemia or lack of normal antibodies)
- Some people with severe autoimmune diseases such as systemic lupus erythematosus (SLE) may have significant immune system suppression

What else could cause a weakened immune system?

Immunosuppressive medications or other treatments such as:

- High-dose oral or intravenous steroid therapy for 2 weeks or longer within the past month. (For example, with prednisone, $\geq 2\text{mg/kg}$ per day for 2 weeks or longer within the past month is considered immunosuppressive.)

VIS SUPPLEMENT D: A Weakened Immune System Means You Should Not Get Smallpox Vaccine

(continued from previous page)

- Cancer chemotherapy agents within the past 3 months
- Radiation therapy within the past 3 months.
- Organ or bone marrow transplant
- Medications that suppress the immune system, including steroids, some drugs for autoimmune disease, or drugs taken in association with an organ or bone marrow transplant (consult your health care provider)

If you have questions about any of the above conditions, please consult your health care provider before being vaccinated.

More on HIV/AIDS

Up to 300,000 people in the U.S. may be infected with the HIV virus and not know it. You can have HIV infection and seem to be completely well. Although you may seem fine, if you have HIV, you are at risk for a bad reaction from smallpox vaccine. People with conditions such as HIV or AIDS that can suppress their immune system are at higher risk for having a severe skin rash or blood infection from the vaccine.

Below is a list of factors that may place you at higher risk for having HIV infection:

- Use of needles to inject anything not prescribed by your doctor
- Had an accidental needle-stick
- Had sexual contact with someone who has HIV/AIDS or has had a positive test for HIV/AIDS
- Had sexual contact with a prostitute or someone else who takes money or drugs or payment for sex
- Had sexual contact with someone who ever has used needles to inject anything not prescribed by a doctor
- For women: Had sexual contact with a man who has ever had sexual contact with another man
- For men: Had sexual contact with another man

If any of these situations apply to you, talk to your health care provider about getting tested for HIV before being vaccinated. In addition, since some people with HIV do not have these risk factors, if you have any concerns please get tested.

How can I learn more?

If have any questions about whether your immune system may be weakened, consult your health care provider before getting 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 VACCINE INFORMATION STATEMENT (VIS) SUPPLEMENT E****Pregnancy and Breastfeeding Mean You Should Not Get Smallpox Vaccine**

The smallpox vaccine is made from a live virus related to smallpox called vaccinia (not smallpox virus). The vaccine stimulates the immune system to react against the vaccinia virus, and develop immunity to it. Immunity to vaccinia also provides immunity to smallpox. For most people, live virus vaccines are safe and effective. In pregnant women, however, smallpox vaccination can cause an infection in the unborn child that can lead to premature delivery, skin rash with scarring, stillbirth, or death of the child after delivery. In addition, it is unknown whether vaccine virus or antibodies are excreted in breast milk. Also, the close physical contact that occurs during breastfeeding increases the chances of accidentally transferring the virus from the vaccination site to the baby.

Pregnancy

- **Pregnant woman should not get the smallpox vaccine.**
- Also, if someone you are in **close physical contact** with is **pregnant**, you should **not get the smallpox vaccine**. (Close contacts include anyone living in your household and anyone you have close physical contact with such as a sexual partner.)
- Women who are vaccinated should **avoid getting pregnant for 4 weeks**.

If you want to get the smallpox vaccine

- Any woman who thinks she could be pregnant or who wants additional assurance that she is not pregnant should perform a morning urine pregnancy test on the day vaccination is scheduled.

After vaccination, prevent pregnancy for a month:

You should wait until the vaccination site has completely healed and the scab has fallen off before you try to become pregnant after vaccination. Take measures to prevent becoming pregnant.

Breastfeeding

- **Women who are breastfeeding should not get the vaccine.** This applies to women who are breastfeeding as well as pumping and then bottle-feeding breast milk.
- Breastfeeding by a close contact is not a contraindication to vaccination. You can get vaccinated if a close contact is breastfeeding.

What if there is an outbreak of smallpox?

If there is a smallpox outbreak, recommendations on who should get vaccinated will change. Anyone who is exposed to smallpox should get vaccinated because they will be at greater risk from the disease than they are from the vaccine. Public health authorities will recommend who should be vaccinated at that time and what measures you can take to try to protect yourself from being exposed to smallpox.

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)



Pre-Event Screening Worksheet for Smallpox Vaccine

The smallpox vaccine contains a live virus that is closely related to the smallpox virus. Most people who receive this vaccine will not have any adverse reactions. However, some people should not receive the vaccine because they are at risk of having problems following vaccination.

The smallpox vaccine is not like most other vaccines you may have received in the past. The vaccine virus can be spread from person to person, which means that problems following vaccination can occur both in the vaccinated person and his or her close contacts. Your close contacts include everyone who lives in your household and anyone that you have close, physical contact with (such as a sex partner). Before being vaccinated, you should find out if you and your close contacts have any of the conditions listed below. Also write down the names and doses of all prescription medications that you and your close contacts take. Talk with your doctor or pharmacist if you are not sure.

This worksheet contains questions designed to help you determine if you should not receive smallpox vaccine because of certain medical conditions that would place you or your close contacts at risk for a serious reaction from the vaccine. If you determine that you should not receive this vaccine, then you should not attend the vaccination clinic. Otherwise, you should bring the worksheet to the vaccination clinic after filling it out. If you are not sure about some responses, you should try to get the answers from your doctor before going to the vaccination clinic.

Some of these questions are of a personal and sensitive nature. This worksheet will not be collected by those administering the smallpox vaccine.

Who should not receive smallpox vaccine?

You should NOT receive the smallpox vaccine if you or a close contact has any of the conditions listed below. Close contacts include anyone living in your household and anyone you have close, physical contact with (such as a sex partner). Friends or people you work with are not considered close contacts.

- Known or suspected HIV/AIDS infection.
- A condition that impairs the immune system like leukemia, lymphoma, or a primary immune deficiency disorder.
- Some severe autoimmune diseases such as systemic lupus erythematosus (SLE) that may significantly suppress the immune system.
- Use drugs that affect the immune system, like oral steroids (prednisone and related drugs), some drugs given for autoimmune diseases, or drugs taken in association with an organ or bone marrow transplant.
- Are receiving or recently received chemotherapy or radiation therapy for cancer.
- Currently pregnant or might become pregnant within 4 weeks after smallpox vaccination. **Any woman who might be pregnant should perform a pregnancy test with a "first morning" urine sample on the day of vaccination.**
- Some skin diseases in childhood or adulthood, including atopic dermatitis or eczema.
- A history (as a child or adult) of a RECURRING itchy, red rash that lasted more than 2 weeks and was located in the creases of the arms or legs (even if currently resolved).

Pre-Event Screening Worksheet for Smallpox Vaccine

(continued from previous page)

- Darier's disease (keratosis follicularis), a skin disease that usually begins in childhood.
- Had a serious, life-threatening reaction to smallpox vaccine in the past (does not apply to close contacts).

Who should delay vaccination?

You should delay receiving the smallpox vaccine if you meet any of the following criteria:

- You are currently breastfeeding
- You (or a close contact) currently have a skin problem that causes significant breaks in the skin surface, such as burns, severe acne, impetigo, chickenpox, shingles, poison ivy, or other rashes (including those caused by prescription medications).
- You are currently using steroid drops in your eyes.
- You have a moderate or severe illness (including an illness with a fever).

You can receive the smallpox vaccine after the acute illness or rash goes away, or after you stop using these medications, and your doctor approves the vaccination.

What about HIV infection?

Up to 300,000 people in the United States may be infected with the HIV virus and do not know it. You can have HIV infection and feel completely well. Although you may seem fine, if you have HIV infection you are at risk for serious, life-threatening reactions from this vaccine. If you do not know your HIV status, you should talk with your private doctor to decide if you should be tested before volunteering to get vaccinated. People with conditions such as HIV or AIDS that can suppress their immune system are at higher risk for having severe adverse events after vaccination.

Below is a list of factors that may place you at higher risk for having HIV infection. If any of these apply to you, you should strongly consider being tested for HIV before getting the smallpox vaccine. In addition, since some people with HIV do not have these risk factors, if you have any concerns please get tested.

1. Use of needles to inject anything not prescribed by your doctor
2. Had an accidental needle-stick
3. Had sexual contact with someone who has HIV/AIDS or has had a positive test for HIV/AIDS virus
4. Had sexual contact with a prostitute or someone else who takes money or drugs or payment for sex
5. Had sexual contact with someone who has ever used needles to inject anything not prescribed by a doctor
6. For women: Had sexual contact with a man who has ever had sexual contact with another male
7. For men: Had sexual contact with another man

Screening questions

Please answer the questions on the following pages to help you determine if you should not get smallpox vaccine due to medical conditions or treatments that place you or your close contacts at greater risk for adverse reactions. Answer each question to the best of your knowledge. You may ask your health care provider or a clinic health care provider for assistance if you do not understand a question. If you need 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)

Pre-Event Screening Worksheet for Smallpox Vaccine

(continued from previous page)

Conditions	Do you have this condition?	Does a close contact have this condition?
1. Currently have cancer, or been treated for cancer within 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
2. 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
3. A disease that affects the immune system like 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
4. An autoimmune disease such as systemic lupus erythematosus (SLE), that may suppress the immune system	<input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated until you check with your doctor	<input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated until you check with your contact's doctor
5. Currently pregnant or might be pregnant. <i>A pregnancy test is recommended if there is ANY chance you might be pregnant</i> (When did your last menstrual period begin? _____/_____/_____)	FEMALES ONLY: <input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated	<input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated
6. Currently breastfeeding	<input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Delay vaccination until you are no longer breastfeeding	Not applicable
7. An allergy to polymyxin B, streptomycin, chlortetracycline or neomycin	<input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated	Not applicable

Pre-Event Screening Worksheet for Smallpox Vaccine

(continued from previous page)

Conditions	Do you have this condition?	Does a close contact have this condition?
8. Had a serious, life-threatening reaction to smallpox vaccine at any time in your life	<input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated	Not applicable
9. Have Darier's disease, a skin problem 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
10. Ever given a diagnosis of atopic dermatitis or eczema by a doctor, including 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
11. Currently have a skin problem that causes significant breaks in the skin surface These problems include burns, severe acne, poison ivy, chickenpox, shingles, or other rashes (including those caused by prescription medications)	<input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Delay vaccination until your skin is healed	<input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Delay vaccination until your contact's skin is healed

Please answer 'yes' or 'no' to indicate if you or a close contact is currently receiving any of the following treatments or drugs. *Talk to a health care provider if you are not sure.*

Treatments	Are you receiving this medication or treatment?	Is a close contact receiving this medication or treatment?
12. Intravenous steroids or oral steroid pills or capsules (prednisone or related drugs) taken for 2 weeks or longer within the past month	<input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated Name and dose of medication:	<input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated Name and dose of medication:

Pre-Event Screening Worksheet for Smallpox Vaccine

(continued from previous page)

Treatments	Are you receiving this medication or treatment?	Is a close contact receiving this medication or treatment?
13. Drugs that affect the immune system like methotrexate, cyclophosphamide, and cyclosporine, among others, within the last 3 months	<input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated Name and dose of medication:	<input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated Name and dose of medication:
14. Radiation therapy 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
15. Chemotherapy 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
16. Currently use steroid drops in your eyes	<input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated	Not applicable

17. Do you currently have a moderate or severe illness?

- YES → You must wait until this illness goes away before you get vaccinated
- NO

Some individuals may not be sure if they have had eczema or atopic dermatitis. The following questions are designed to help you determine if you should not get vaccinated because you or a close contact may have a history of atopic dermatitis or eczema.

18. 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 may have eczema or atopic dermatitis. You should discuss this possibility with your doctor. Please answer questions 19 and 20.
- NO → **SKIP TO question 21**
- 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:

Pre-Event Screening Worksheet for Smallpox Vaccine

(continued from previous page)

19. 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

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

- YES
- NO → **SKIP TO question 21**
- Don't know

IF 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

21. Does a close contact currently have an **itchy red rash** that comes and goes but usually lasts more than 2 weeks, or did a close contact have this condition as a baby or child?

- YES → Your close contact may have eczema or atopic dermatitis. Discuss this possibility with a doctor.
- NO
- Don't know → You need to find out more about your contact's rash before getting vaccinated.

If you answered 'YES' or 'Don't know' to question 21, more information is needed about your close contact before you get the smallpox vaccine. If you do not know the answers to the questions below, please ask the appropriate person to help you answer them. A parent should answer these questions if they apply to a child.

22. 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 23 and 24 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:

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

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

Pre-Event Screening Worksheet for Smallpox Vaccine

(continued from previous page)

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

- YES
- NO
- Don't know

IF 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

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)

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January 23, 2003

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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

If someone you have close, physical contact with (your spouse, partner or other member of your household) is considering getting the smallpox vaccine, there are some things you should know.

Before Vaccination: What You Should Know

The smallpox vaccine contains a live virus called vaccinia, which is related to smallpox, though milder. The vaccine helps the body develop immunity to smallpox. And while the smallpox vaccine is safe and effective for most who receive it, 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 (household or similar intimate physical contact) with someone who has been vaccinated.

Careful screening measures are in place to help ensure that people who are more susceptible to serious reactions, or who live with others who are more susceptible to serious reactions, are not vaccinated. As your close contact considers vaccination, it's important that you actively participate in this screening process. Inform your close contact if you have any of the conditions listed below, or even if you have any concerns about any of the conditions listed below.

Health conditions that would mean you should not be in close contact with someone who has been vaccinated are:

- A diagnosis of eczema or atopic dermatitis, past or present
- A weakened immune system, for whatever reason (HIV, cancer and cancer treatment, some autoimmune diseases and some treatments for autoimmune conditions can weaken the immune system)
- A skin condition with breaks in the skin (chickenpox, shingles, burns, severe acne, etc...) or
- Pregnancy

If any of these conditions apply to you, you should not be in close contact with someone who has gotten smallpox vaccine because of the risk it poses to you (or your fetus if you are pregnant).

After Vaccination: What You Should Know

If neither you nor your close contact has any condition that might place you at increased risk from a serious reaction, and that close contact decides to get vaccinated, there are still some things you should keep in mind.

The main concern for people who have close, physical contact with someone who has gotten the vaccine is that the vaccinia virus can be spread from the vaccination site, causing rash (mild to severe), fever, and head and body aches. Vaccinia is spread by touching a vaccination site before it has healed or by touching bandages, clothing, or other material contaminated with live virus from the vaccination site and then touching another part of the body or touching someone else. The vaccination site often becomes itchy, which may lead to scratching, rubbing, or touching the site.

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

In the past, when vaccinated persons spread vaccinia to other parts of their body, it often was to their eyes or their genitals. Vaccinated persons also can spread vaccinia to other individuals. In the past, this was reported to occur between 20 and 60 times out of 1 million people vaccinated for the first time and often involved children. Most of the time, this took place in situations of close contact, such as happens in a household, or in similar situations involving close physical contact where careful hand hygiene and site care may not be followed.

After Vaccination: Taking Care

People getting the vaccine will receive instructions for special care to minimize the risk of spreading vaccinia by touch, but you also can take precautions to protect yourself. These measures should be followed until the scab that forms at the vaccination site after vaccination falls off on its own (in 2 to 3 weeks).

- Do not touch the vaccine site or any materials that might be contaminated with live virus from the site (such as bandages, towels, clothing, or washcloths used by the person who got the vaccine).
- If you accidentally come in contact with the vaccine site, or something that may be contaminated with live virus, immediately wash with soap and warm water.
- If you share a bed with the vaccinated person, be sure that they are wearing a gauze bandage held in place with first aid adhesive tape over the vaccination site. As an extra precaution, the person who got the vaccine can wear a shirt or pajamas that cover the bandaged vaccine site. If they do not, you may choose to sleep in a separate bed. (When involved in direct patient care, healthcare workers should cover the gauze with a semipermeable dressing as an additional barrier.)
- Keep a separate laundry hamper for items like clothing, towels, or bedding that have come in direct contact with the vaccine site or drainage from the site. Launder these items, using warm water with detergent and/or bleach and wash hands carefully afterwards.
- Remind the person who got the vaccine to follow site care and hand washing instructions. If their hand is contaminated and they touch you, you can contract vaccinia.

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 SUPPLEMENTAL FACT SHEET****Investigational Vaccinia Immune Globulin (VIG) Information**

The smallpox vaccine is made from a live virus related to smallpox called vaccinia (not smallpox virus). The vaccine stimulates the immune system to react against the vaccinia virus, and develop immunity to it. Immunity to vaccinia also provides immunity to smallpox. For most people, live virus vaccines are safe and effective. Some people, however, are at greater risk for serious side effects from the smallpox vaccine. Vaccinia Immune Globulin (VIG) may help people who have certain serious reactions to the smallpox vaccine. VIG is an investigational new drug (IND) made from plasma from the blood of people who have immunity to smallpox. If you develop a serious reaction to the smallpox vaccine, you may be offered VIG.

VIG Information

- VIG is an immune globulin made from the blood of people who have gotten the smallpox vaccine more than once (usually many times). The part of the blood (antibodies) that gives protection from vaccinia infection is taken out, purified (cleaned), and bottled. It is called the immune globulin.
- VIG is not licensed (approved) by the Food and Drug Administration (FDA). It is "investigational."
- There are two available types of VIG: VIG-intramuscular (VIG-IM) and VIG-intravenous (VIG-IV).
- VIG might be used in cases of generalized vaccinia, eczema vaccinatum, or progressive vaccinia.

How is VIG administered?

VIG is given by a needle in the muscle in the arm (VIG-IM), or by a needle in a vein in the arm (VIG-IV). The type of VIG (IM vs. IV) given will depend on which is available.

Side Effects

- VIG is made from human blood plasma. Products made from human blood may contain infectious agents, such as viruses, that can cause disease. To decrease the chance that such products carry viruses, plasma donors are checked for prior contact with certain viruses, the collected plasma is treated for the presence of certain viruses, which are killed and/or removed from the plasma.
- Immune globulin products like VIG may cause allergic reactions that can be mild or may be serious and cause life-threatening breathing and heart problems. If you have a serious or life-threatening reaction, medical care and drugs are available to treat you.
- People who have a problem making a certain antibody called IgA or who have had a serious allergic reaction to human antibody products before are at risk for an allergic reaction to VIG.
- Most side effects from similar products are mild and do not last for very long. You may experience back pain, chills, headache, muscle pain, joint pain, itching, weakness, fever, nausea, vomiting, abdominal cramps, flushing, tightness of the chest, sweating, changes in blood pressure, dizziness, paleness, shortness of breath, and wheezing. Rashes occur rarely.
- Some people experience pain and soreness at or near the site where VIG is given. While this is unpleasant, it is not serious and can be treated with common pain relievers.

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 SUPPLEMENTAL FACT SHEET****Investigational Vistide® (Cidofovir) Information**

The smallpox vaccine is made from a live virus related to smallpox called vaccinia (not smallpox virus). The vaccine stimulates the immune system to react against the vaccinia virus, and develop immunity to it. Immunity to vaccinia also provides immunity to smallpox. For most people, live virus vaccines are safe and effective. Some people, however, are at greater risk for serious side effects from the smallpox vaccine.

Vistide (cidofovir), a drug licensed to treat serious viral infections of the eye in HIV-infected people, may help people who have certain serious reactions to the smallpox vaccine. If you develop a serious reaction to the smallpox vaccine, and VIG (another medicine used to treat bad reactions to the smallpox vaccine) is not available or is not working, you may be offered cidofovir. While this drug has not been used to treat patients with bad reactions to smallpox vaccine, early results from laboratory studies suggest that cidofovir may work against the vaccinia virus. Use of cidofovir would be administered under an Investigational New Drug (IND) protocol.

Cidofovir Information:

- Vistide® (Cidofovir) is licensed to treat cytomegalovirus (CMV) retinitis (a serious eye infection) in HIV-infected people. It is not licensed to treat the problems caused by smallpox vaccine so it is only available through a special protocol called an Investigational New Drug (IND) protocol.
- Use of cidofovir to treat smallpox vaccine reactions should be evaluated and monitored by experts at the National Institutes of Health and the Centers for Disease Control and Prevention.
- Cidofovir might be used to treat generalized vaccinia, eczema vaccinatum, or progressive vaccinia.

How is cidofovir administered?

Cidofovir is injected through a needle in the vein. Fluids will be given through the vein and another medication (probenecid) given by mouth both before and after cidofovir. These may help decrease the side effects of cidofovir.

Side Effects:

- Kidney problems that can lead to kidney failure.
- Low white blood cells.
- Pressure in the eye.
- Swelling and tenderness of the eye.
- Build up of acid in the body that can result in liver problems and inflammation of the pancreas that can result in death.
- Other problems include fever, infection, pneumonia, shortness of breath and nausea with vomiting.
- Cidofovir can cause headache, weakness, rash, hair loss, diarrhea, pain, lowered number of red blood cells, loss of appetite, chills, coughing, and infections in the mouth.

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Patient Medical History and Consent Form

For Administrative Use Only:

Initial Vaccination:

Revaccination: (Initial Patient Vaccination Number (PVN) _____)

Date: ___/___/___ (mm/dd/yyyy)

*For Administrative Use Only: Place
Patient Vaccination Number (PVN)
Sticker here*

Please fill out sections A, B, and D of this form. Please use ink and print.

SECTION A: PATIENT DEMOGRAPHIC INFORMATION

(To be filled out by the patient. Please use ink and print)

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

Last Name: _____ **Suffix** (Jr. Sr., M.D., etc.): _____

SSN: ____-____-____ **Date of Birth:** ___/___/____ (mm/dd/yyyy)

Gender: Male Female

Street Address: _____ **Apt. #:** _____

City: _____ **State:** _____ **Zip code:** _____

County _____

Contact Information:

Home Phone: (____) ____ - ____

Work: (____) ____ - ____ ext. ____

Cell Phone: (____) ____ - ____

Fax: (____) ____ - ____

E-Mail Address: _____

Occupation: _____ **Employer** _____

Employer's Address _____

Ethnicity/Race: Hispanic or Latino Asian African American Hawaiian
 American Indian or Alaskan White

May we contact you in the future to discuss your vaccination experience? Yes No

SECTION B: VACCINATION AND MEDICAL HISTORY

(To be filled out by the patient. Please use ink and print)

Vaccination History

Did you ever receive the smallpox vaccine? Use the most recent date if you were vaccinated more than once.

I have documentation that I was vaccinated on this date: ___/___/____ (mm/dd/yyyy)

I recall that I was vaccinated on this date, but I don't have documentation: ___/___/____ (mm/dd/yyyy)

I was vaccinated in childhood, but I don't know the date.

No, I was never vaccinated or I don't know.

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

Did you have any bad reactions to the vaccine (adverse events)? Yes No or Don't know

If yes, please describe the reaction _____

Date: __/__/____ (mm/dd/yyyy)

Patient Name: _____ PVN: _____

Medical History

Have you received chickenpox (varicella) vaccination in the last month? Yes No

Are you currently taking medication? Yes No

If yes, please list medications: _____

Are you sick today? Yes No

If yes, please describe your illness (you may need to wait to be vaccinated until you get better) _____

Do YOU have any of the following conditions? Yes No

1. Conditions that weaken the immune system such as HIV/AIDS, leukemia, lymphoma, or most other cancers, organ transplant, or agammaglobulinemia.
2. A severe autoimmune disease such as systemic lupus erythematosus (SLE) that may significantly suppress the immune system.
3. Currently taking, or have recently been treated with, immunosuppressive drugs like oral steroids (e.g. prednisone), some drugs for autoimmune disease, or drugs taken after an organ transplant.
4. Taking cancer treatment with drugs or radiation or have taken such treatment in the past three months.
5. Eczema or atopic dermatitis or a history of these conditions, even in childhood or infancy.
6. Other skin conditions that cause breaks in the skin such as an allergic rash, severe burn, impetigo, chickenpox, shingles, or severe acne.
7. Currently being treated with steroid eye drops.
8. Currently pregnant, breastfeeding, or planning to become pregnant in the next month.
9. Ever had a life-threatening allergic reaction to antibiotics polymixin B, streptomycin, chlortetracycline, neomycin or a previous dose of smallpox vaccine.

IF YOU ANSWERED YES, YOU SHOULD NOT GET THE VACCINE AT THIS TIME.

Do any of your HOUSEHOLD MEMBERS OR CLOSE PHYSICAL CONTACTS have any of the following conditions? Yes No

(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 co-workers.)

1. Conditions that weaken the immune system such as HIV/AIDS, leukemia, lymphoma, or most other cancers, organ transplant, or agammaglobulinemia.
2. A severe autoimmune disease such as systemic lupus erythematosus (SLE) that may significantly suppress the immune system.
3. Currently taking, or have recently been treated with, immunosuppressive drugs like oral steroids (e.g. prednisone), some drugs for autoimmune disease, or drugs taken after an organ transplant.
4. Taking cancer treatment with drugs or radiation or have taken such treatment in the past three months.
5. Eczema or atopic dermatitis or a history of these conditions, even in childhood or infancy.
6. Other skin conditions that cause breaks in the skin such as an allergic rash, severe burn, impetigo, chickenpox, shingles, or severe acne.
7. Currently pregnant or planning to become pregnant in the next month

IF YOU ANSWERED YES, YOU SHOULD NOT GET THE VACCINE AT THIS TIME.

Screener comments/notes for clarification (for administrative use only) _____

SECTION C: CURRENT VACCINATION INFORMATION AND TAKE EVALUATION

(This section will be filled in by clinic staff)

Date: ___/___/___ (mm/dd/yyyy)

Patient Name: _____ PVN: _____

DISPOSITION

<input type="checkbox"/> Referred for Vaccination	<input type="checkbox"/> Deferred due to medical contraindications
<input type="checkbox"/> Vaccination refused	

Clinic personnel should pre-enter or attach this information before printing and copying the form.

Vaccination Clinic Information		Vaccine Batch Information			
Name:		Vaccine Type:		Batch #:	
Contact:		Program:		Batch Date:	
Phone:		Dilution Strength:			
Fax:		Vaccine Lot#:		Diluent Lot #:	
Address:		Vaccine Lot Manufacturer:		Diluent Lot Manufacturer:	

Referring Organization _____ Address _____ Date of Vaccination: ___/___/___ Arm inoculated: <input type="checkbox"/> Left <input type="checkbox"/> Right Vaccine Administered by: _____ (please enter first name, last name, and professional suffix (M.D., R.N., etc))
--

Take Response

If take response evaluation is going to be conducted at another clinic site, please copy this page and send it to that location.

Take Response Clinic: Name _____ Address _____ Take Response Exam performed by: _____ (please enter first name, last name, and professional suffix (M.D., R.N., etc))	Exam Date: ___/___/___ <input type="checkbox"/> Major <input type="checkbox"/> Equivocal <input type="checkbox"/> No Take
Additional Comments	

Adverse Events should be recorded in VAERS

**SECTION D: CONSENT SIGNATURE
(TO BE RETAINED BY THE VACCINATION CLINIC)**

Date: ___/___/___ (mm/dd/yyyy)

Patient Name: _____ PVN: _____

I have:

- Received, read and understand the Smallpox Pre-Vaccination Information Package, including 1) the Vaccine Information Statement (VIS), 2) the VIS supplements (A-E) on reactions after smallpox vaccination, vaccination site appearance and care, skin conditions, weakened immune system, pregnancy and breastfeeding, and 3) the pre-event screening worksheet;
- Considered my own health status as well as the health status of my household members and close physical contacts;
- Had the opportunity to discuss my medical concerns with my healthcare 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 the decision to be vaccinated is voluntary and agree to proceed with smallpox vaccination.

Patient Signature

Date

Medical Screener

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. Identifiable information may be shared with authorized U.S. Department of Health & Human Services' personnel and public health or cooperating medical authorities.



Post-Vaccination and Follow-Up Information Sheet

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

You have just been vaccinated with Smallpox Vaccine; please do not throw this sheet away. This sheet will serve as your proof of vaccination until you come back to the clinic for your vaccination site exam. On that date, you will get your permanent immunization card.

INTERIM PROOF OF VACCINATION:

Name: _____

Date vaccinated: _____

Clinic: _____

Clinic Telephone No.: _____

APPOINTMENT FOR REQUIRED VACCINATION SITE EXAM:

Date of Appointment: _____

Clinic: _____

Clinic Telephone No.: _____

WHAT TO DO 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. YOU WILL NEED TO BRING IT WITH YOU WHEN YOU RETURN FOR YOUR VACCINATION SITE EXAM.

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