

The University of Iowa
Vaccinia Vaccination
Information Form

I understand that due to my occupational exposure to vaccinia virus, I may be at risk of acquiring infection from vaccinia. I have been given the opportunity to be vaccinated with the smallpox vaccine, at no charge to myself.

After reading the Medication Guide and information packet from the Centers for Disease Control and Prevention (CDC) I understand there are risks involved in working with vaccinia virus, in addition to risks in receiving the vaccination. My signature below indicates that I have:

1. Read the CDC's Medication Guide that has been provided to me (follows this informational form).
2. Read the CDC's "Important Information about Vaccinia (Smallpox) Vaccine *For Laboratory Workers*" that has been provided to me (follows this informational form).
3. Had an opportunity to ask questions about vaccinia with Biosafety Staff in the Environmental Health and Safety Office (EHS) at 335-8501.
4. Had the opportunity to ask questions about the vaccine with University Employee Health Clinic staff at 356-3631.

I have decided to:

Decline the vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring an infection from vaccinia. If I continue to have occupational exposure to this virus and decide to be vaccinated in the future, I may request and receive the vaccination, at no charge to myself.

Receive the vaccine, provided through the University Employee Health Clinic (UEHC).

Signature: _____

Please print name: _____

Date: _____

University ID number: _____

Principal Investigator/Lab Director Name: _____

If consenting, please also complete:

Date of Birth: _____

Job Title: _____

List of duties and/or viruses used in lab that may cause exposure to vaccinia virus:

Return page 1 of this form to: Associate Biosafety Officer, 100 EHS.

Medication Guide
Smallpox (Vaccinia) Vaccine, Live
ACAM2000[®]

Please read this Medication Guide before you receive a vaccination with ACAM2000. This Guide does not take the place of talking to your healthcare provider about ACAM2000 and the smallpox disease.

**What is the most important information I should know about
the ACAM2000 smallpox vaccine?**

- **If you are at a high risk for being exposed to smallpox, you should be vaccinated even if you have health problems, unless you have certain problems with your immune system.** People who have health problems may have a higher chance of getting serious side effects from vaccination but are also those who have a higher chance of dying from the smallpox disease.
- **ACAM2000 may cause serious heart problems called myocarditis and pericarditis, or swelling of the heart tissues.** In studies, about 1 in every 175 persons who got the vaccine for the first time may have experienced myocarditis and/or pericarditis. On rare occasions these conditions can result in an irregular heart beat and death. Your chances of getting heart problems from the vaccine are lower if you have already had this vaccine before. You can have myocarditis and/or pericarditis even if you have no symptoms. **Call your healthcare provider or get emergency help right away if you have:**
 - **chest pain or pressure**
 - **fast or irregular heartbeat**
 - **breathing problems**

See “What are the possible side effects of ACAM2000?”

- **Because the vaccine has a live virus, it can spread to other parts of your body or to other people if you touch the vaccination site and then touch other parts of your body or other people.** The vaccine virus can spread until the vaccination scab falls off (2 to 4 weeks after vaccination). **If the virus is spread to a person who should not get the vaccine, the side effects can be very serious and life-threatening.**

See “How do I care for the smallpox vaccination site?”

What is the ACAM2000 smallpox vaccine?

ACAM2000 is a prescription vaccine used to protect people against smallpox disease. It is for use in people who have a high chance of getting the disease.

ACAM2000 contains live vaccinia virus (a “pox”-type virus) to protect against smallpox disease.

Who should not get the ACAM2000 smallpox vaccine?

- **In an emergency, you should be vaccinated if you are at high risk for getting smallpox disease even if you have health problems (except if you have certain problems with your immune system as discussed below).**
- Your healthcare provider may not give you ACAM2000 if you have problems with your immune system. You may have immune system problems if you:
 - have leukemia
 - have lymphoma
 - have had a bone marrow or organ transplant
 - have cancer that has spread
 - have HIV, AIDS
 - have cellular or humoral immune deficiency
 - are being treated with radiation
 - are being treated with steroids, prednisone, or cancer drugs

How do I receive ACAM2000?

ACAM2000 smallpox vaccine is not a shot like other vaccines. Your healthcare provider will make 15 pokes in the skin of your upper arm with a needle containing ACAM2000. The pokes are not deep, but will cause a drop of blood to form. This is called the vaccination site.

It is important to care for the vaccination site properly so that the virus doesn't spread to other parts of your body or to other people. You can infect another part of your body or other people until the scab falls off.

How do I care for the ACAM2000 vaccination site?

It is important to ALWAYS:

- 1. Wear bandages to cover the entire vaccination site.**
- 2. Wear sleeves to cover the site.**
- 3. Wash your hands, wash your hands, wash your hands.**

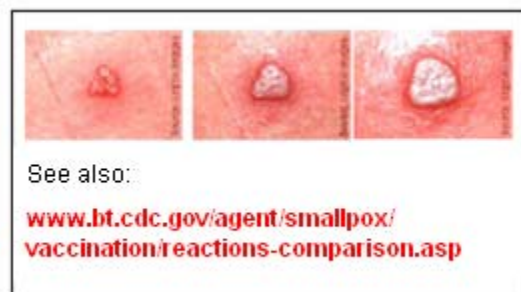
- **When changing bandages or caring for your vaccination site, wear gloves. Use an absorbent bandage to completely cover your vaccination site.**
 - Change your bandage when it begins to soak through (at least every 1 to 3 days).
 - Throw away gloves and used bandages in sealed or double plastic bags. A small amount of bleach can be added to the bag to kill the virus.
- **Wear clothes with sleeves to cover the site and prevent scratching the vaccination site.** It is especially important to wear a bandage and sleeves to bed to avoid scratching.
- **Wash your hands frequently** with alcohol-based cleansers or soap and water.

- Be sure to wash your hands each time you change your bandage or if you touch the vaccination site.
- Do not use creams or ointments on the vaccination site because they will delay healing and can spread the virus.
- Do not scratch or pick at the vaccination site.
- You can take a bath or shower, but don't touch or scrub the vaccination site.
 - It is best to cover the vaccination site with a waterproof bandage.
 - If the vaccination site gets wet, dry the site with toilet paper and flush it. (Do not use a cloth towel because it can spread the virus.)
 - Cover the vaccination site with a loose gauze bandage after bathing to allow it to dry out.
- Do not use a bandage that blocks air from the vaccination site. This could cause the skin at the vaccination site to soften and wear away.
- If you exercise enough to cause sweat to drip, use a waterproof bandage on the vaccination site when exercising.
- Wash clothing, towels, bedding or other items that may have come in contact with the vaccination site separately from other wash. Use hot water with detergent and bleach.
- When the scab falls off, throw it away in a sealed plastic bag with a small amount of bleach. Wash your hands afterwards.

What should I expect at the vaccination site and in the weeks following vaccination?

- If vaccination is successful, a red and itchy bump forms at the vaccination site in 2 to 5 days. Over the next few days, the bump becomes a blister and fills with pus. During the second week, the blister dries up and a scab forms. The scab falls off after 2 to 4 weeks, leaving a scar. People vaccinated for the first time may have a larger reaction than those being revaccinated. See expected responses below:

Smallpox Vaccination Site: expected response after vaccination



Note: After 6 to 8 days, check to be sure that your vaccination site looks like one of the pictures above. If it does not look like this, see your healthcare provider because you may need to be revaccinated.

- If you need medical care in the month after your vaccination, tell your healthcare provider you just got a smallpox vaccination.
- Certain people, such as laboratory workers who work with smallpox, are at risk of being exposed to smallpox over a long period of time. These people may need a booster vaccination every 3 years to maintain protection against smallpox.

What should I avoid after getting vaccinated with the ACAM2000 smallpox vaccine?

- **For 4 weeks after vaccination AND until the vaccination site has healed, you should avoid:**
 - **getting pregnant.** Smallpox vaccine may rarely cause infection in an unborn baby if the mother is vaccinated during pregnancy. This infection usually results in stillbirth or death.
 - **handling babies or breastfeeding.**
 - **swimming or hot tub use.**
 - **donating blood.**
 - **Tuberculin (TB) testing.** Smallpox vaccine may cause the TB test to give the wrong result.
- Avoid rubbing, scratching or touching the vaccination site.
- Until the vaccination scab falls off, do **NOT**:
 - have contact with people who cannot get the vaccine to prevent accidental spread of the vaccine virus. This includes physical contact and household contact. If there is someone in your household who should not get the vaccine, such as a pregnant woman, an infant, or someone who has an illness, you should not stay in the house until the vaccination scab falls off.
 - share a bed, clothes, towels, linen, or toiletries with unvaccinated people.



Don't scratch that itch.
Vaccine virus can accidentally spread to a family member, close contact, or another part of your body.



- We don't know if the vaccine virus can be spread to cats, dogs, or other household pets, or whether pets can spread the virus to other people in the household. Try to keep the vaccine virus from reaching your pet. See "**How do I care for the smallpox vaccination site?**"

What are the possible side effects of ACAM2000?

ACAM2000 may cause serious heart problems, including myocarditis and pericarditis. This can happen within 3 to 4 weeks after you get the vaccine. Call your healthcare provider or get emergency help right away if you have:

- chest pain or pressure
- fast or irregular heartbeat
- breathing problems

Most people who get myocarditis and/or pericarditis seem to get better after a few weeks. But heart problems may last longer in some people, and in rare cases, could lead to death.

Other serious side effects include:

- swelling of the brain or spinal cord
- problems with the vaccination site blister, such as it becoming infected
- spreading of the vaccine virus to other parts of your body or to another person
- severe allergic reaction after vaccination
- accidental infection of the eye (which may cause swelling of the cornea causing watery painful eyes and blurred vision, scarring of the cornea, and blindness)

Common side effects include:

- itching
- swollen lymph nodes
- sore arm
- fever
- headache
- body ache
- mild rash
- fatigue

The risks for serious vaccine side effects are greater for people who:

- have skin problems called eczema or atopic dermatitis
- have skin problems, such as burns, impetigo, contact dermatitis, chickenpox, shingles, psoriasis, or uncontrolled acne
- have had heart problems
- have serious heart or blood vessel problems including angina, previous heart attack, artery disease, congestive heart failure, stroke, or other cardiac problems
- smoke or have high blood pressure, high cholesterol, diabetes, high blood sugar, or a family history of heart problems
- are breastfeeding
- are pregnant, could be pregnant, or plan to become pregnant
- are less than 1 year old
- are taking steroid eye drops or ointment

- have had problems after previous doses or are allergic to ACAM2000 or any part of ACAM2000 such as antibiotics neomycin or polymyxin B

Tell your healthcare provider if you have any of the above conditions.

The virus from your vaccination can spread to other people and cause serious side effects. It is important to tell your healthcare provider if you:

- live or work with a person who has skin problems (like eczema, dermatitis, burns, psoriasis, bad acne) or is suffering from impetigo, chickenpox or shingles
- live or have close contact with a baby, or a person who is pregnant or breastfeeding
- live or have close contact with a person who has an immune deficiency or cardiac disease

See “How do I care for the ACAM2000 vaccination site?”

Tell your healthcare provider about any side effect that bothers you or that does not go away.

To report SUSPECTED SIDE EFFECTS (ADVERSE REACTIONS), contact sanofi pasteur Inc. at 1-800-822-2463 (1-800-VACCINE) or VAERS at 800-822-7967 and <https://vaers.hhs.gov>

General information about the safe and effective use of ACAM2000

This Medication Guide provides a summary of the most important information about ACAM2000. Medicines are sometimes prescribed for purposes other than those listed in the Medication Guide. If you would like more information or have any questions, talk to your healthcare provider. You can ask your healthcare provider for information about ACAM2000 that is written for healthcare professionals. You can also visit <http://www.sanofipasteur.us/acam2000>. The vaccine should not be used for a condition other than that for which it is prescribed.

What are the ingredients in ACAM2000?

ACAM2000: live vaccinia virus derived from plaque purification cloning from Dryvax[®] (Wyeth Laboratories, Marietta, PA, calf lymph vaccine, New York City Board of Health Strain) and grown in African Green Monkey kidney (Vero) cells

Inactive ingredients: 6-8 mM HEPES (pH 6.5-7.5), 2% human serum albumin USP, 0.5 – 0.7% sodium chloride USP, 5% mannitol USP, and trace amounts of the antibiotics neomycin and polymyxin B

Diluent for ACAM2000: 50% (v/v) Glycerin USP, 0.25% (v/v) Phenol USP in Water for Injection USP

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Important Information About Vaccinia (Smallpox) Vaccine For Laboratory Workers

Who should receive vaccinia vaccine?

The Centers for Disease Control and Prevention recommends vaccinia vaccine for the following persons:

1. Laboratory workers who directly handle cultures contaminated or infected with vaccinia, recombinant vaccinia, or other orthopoxviruses (such as monkeypox, cowpox, and others);
2. Laboratory workers who directly handle animals contaminated or infected with vaccinia, recombinant vaccinia, or other orthopoxviruses.

Other health-care workers (such as physicians and nurses) whose contact with these viruses is limited to contaminated materials (for example, dressings), but who adhere to appropriate infection control measures, are probably at lower risk for inadvertent infection than laboratory workers. However, because a theoretical risk of infection exists, vaccination may be considered for this group.

Because of the low risk of infection, vaccination is not recommended for persons who do not directly handle virus cultures, or who do not work with materials or animals contaminated or infected with these viruses (for example, security guards, janitorial and engineering personnel).

What are the benefits of vaccinia vaccination?

The immunity to vaccinia should help protect recipients against infection resulting from uncontrolled, inadvertent exposure to vaccinia, recombinant vaccinia, or other orthopoxviruses. These unintentional exposures could occur by unusual routes (for example, splashes into the eye or inhalation of an aerosol). These exposures could also involve a large dose of virus which is more likely to cause illness. In addition, persons with preexisting immunity to vaccinia may be protected against seroconversion to the foreign antigen expressed by a recombinant virus.

How often should I be revaccinated?

More than 95% of persons receiving their first dose of vaccine will develop neutralizing and/or hemagglutination inhibition antibody at a titer of $\geq 1:10$. The level of antibody required for protection against vaccinia infection is not known. Neutralizing antibody appears to persist for many years, with antibody titers of $\geq 1:10$ found in 75% of persons 10 years following a second dose, and up to 30 years following three doses of vaccine. However, fewer than 10% of persons with neutralizing titers of $\geq 1:10$ will have a primary-type response to revaccination, suggesting that these persons are protected from viral replication, and presumably infection. According to data regarding the persistence of neutralizing antibody after vaccination, persons working with nonhighly attenuated vaccinia viruses, recombinant viruses developed from nonhighly attenuated vaccinia viruses, or other nonvariola Orthopoxviruses should be revaccinated at least every 10 years. To ensure an increased level of protection against more virulent nonvariola Orthopoxviruses (e.g., monkeypox), empiric revaccination every 3 years can be considered.

Where can I get more information about vaccinia vaccine?

If you have questions about vaccinia vaccination, you should ask your doctor or the person responsible for vaccination in your facility. The information provided in this handout is based on the Advisory Committee on Immunization Practices vaccinia vaccine recommendations, published in the June 2001

Recommendations and Reports series of *Morbidity and Mortality Weekly Report*. A copy of these recommendations can be found on-line at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5010a1.htm>.

More detailed information regarding ACAM2000TM (adverse events, clinical trial data) can be found in the Acambis (the manufacturer of ACAM2000TM) package insert found on-line at: <http://www.fda.gov/cber/label/acam2000LB.pdf>.

Accidental Vaccinia Virus Exposure: Information Sheet for Laboratory Workers

If you have been exposed to vaccinia virus, or you have had a laboratory accident while working with vaccinia virus:

- **Irrigate the site of exposure*.**

- » If exposure was by needle stick or other route which breaks the skin, wash with soap and water for 5-15 minutes and cover with a bandage.
- » If exposure was by splash to eyes or mucous membranes, irrigate thoroughly for 15 minutes at an appropriate eye wash station.

- **Report to your laboratory supervisor and occupational health IMMEDIATELY.**

- » The occurrence of vaccinia infection and its course will vary depending on route of exposure, the strain of vaccinia, the dose of exposure, your medical history and your "smallpox" (vaccinia virus) vaccine immunization status. Immediate medical "first-aid" interventions may help prevent or lessen the severity of infection.

- **In the weeks following infection take note of the following symptoms which may indicate a need for further medical attention:**

- » Lesions or swelling at the site of exposure
- » Rash
- » Fever

- **If you have already developed lesions that you suspect may be the result of a recent vaccinia Exposure:**

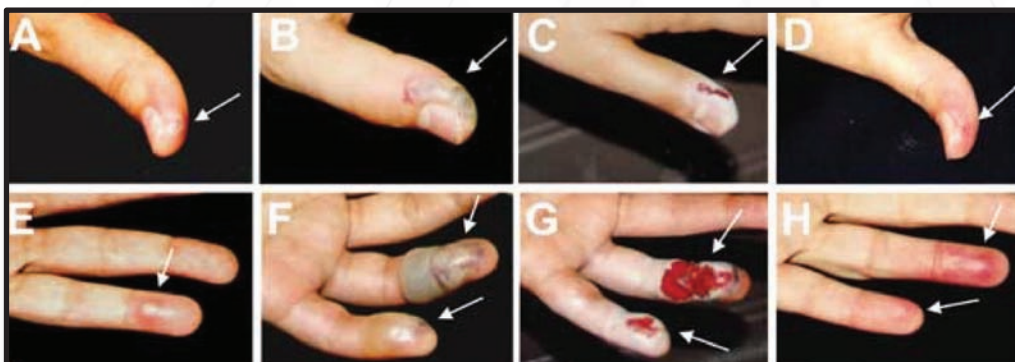
- » Cover the lesions with a bandage
- » Report to your laboratory supervisor and occupational health IMMEDIATELY (if it is after normal business hours, contact occupational health on-call)

- **Provide healthcare personnel with the following information:**

- » Whether or not you ever received a smallpox vaccination
- » Date of your last vaccination
- » The strain of vaccinia you were working with (ex. Western Reserve, Dryvax, MVA)
- » If the strain was recombinant, the identity of the inserted foreign gene
- » The dose/titer of vaccinia exposure (estimate based on concentration of virus suspension, and possible volume of inoculum)

- **The following medical conditions may increase the risk of serious complications. Notify your healthcare provider if you or any of your close contacts:**

- » Have a history of eczema/atopic dermatitis or other active skin conditions, such as acne or psoriasis
- » Have an immunodeficiency or immunosuppressive condition (taking steroids, etc.)
- » Have heart disease
- » Are currently pregnant (or could be pregnant) or nursing



Progression of infection
"G" surgical debridement

Accidental Vaccinia Virus Exposure: Information Sheet for Healthcare Personnel

If you are providing care to someone who has been exposed to vaccinia virus or who is suspected to have an active infection (ex. a laboratory worker or recent recipient of "smallpox" (vaccinia) vaccine), you should know the following:

- Standard barrier precautions should suffice to minimize infection within the health care setting.
- If lesions are active, and mucosal contact may be possible, wear goggles and/or other mucosal protection (mask/faceshield).
- Vaccinia is transmissible by direct CONTACT with lesions or contaminated materials. Risk of transmission immediately after an accidental lab exposure, before virus replication has occurred or lesions have developed, is very small. However, once lesions are present, risk of transmission is increased.
- In addition to barrier precautions, it is preferable that a patient with suspected vaccinia virus infection be cared for by someone who has a history of "smallpox" (vaccinia virus) vaccination.
- **Certain medical conditions may increase the risk of serious complications.** If vaccinated personnel are not available, it is preferable that the patient be cared for by a healthcare provider without any of the following conditions:
 - » History of eczema/atopic dermatitis or other active skin conditions, such as acne or psoriasis
 - » Immunodeficiency or immunosuppressive condition (taking steroids, etc.)
 - » Heart disease
 - » Currently pregnant (or could be pregnant) or nursing
 - » In the instance that a lesion is present, specimens can be submitted to your state or local
- Laboratory Response Network for VACCINIA testing. Contact your local health department for more information. (<http://www.cdc.gov/mmwr/international/relres.html>)
- Treatments that may be considered include vaccinia immune globulin (VIG) or post-exposure vaccination with smallpox vaccine. Contact you state health department or CDC with questions regarding treatment.

CDC Poxvirus Inquiry line: (404) 639-4129

CDC Emergency Operations Center: (770) 488-7100



* Cohen J, Davenport D, Stewart J, Deitchman S, Hillard J, Chapman L, and the B virus working group. CID. 2002. 35: 1191-1203.

Images sources-

- I. Mempel M, Isa G, Klugbauer N, Meyer H, Wildi G, Ring J, et al. Laboratory acquired infection with recombinant vaccinia virus containing an immunomodulating construct. *J Invest Dermatol.* 2003;120:356-8.
- II. Lewis FMT, Chernak E, Goldman E, Li Y, Karem K, Damon IK, et al. Ocular vaccinia infection in laboratory worker, Philadelphia, 2004. *Emerg Infect Dis.* 2006 Jan.
- III. Moussatche N, Tuyama M, Kato SE, Castro AP, Njaine B, Peralta RH, et al. Accidental infection of laboratory worker with vaccinia virus. *Emerg Infect Dis.* 2003;9:724-6.