SMALLPOX VACCINE

WHAT YOU NEED TO KNOW

1 WHAT IS SMALLPOX?

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

Smallpox can also cause—

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

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

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

2 WHAT IS THE SMALLPOX VACCINE?

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

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

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

Getting the vaccine—

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

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

3 WHY GET VACCINATED NOW?

Smallpox vaccine protects people from smallpox.

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

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

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

4 WHO SHOULD GET SMALLPOX VACCINE AND WHEN?

When There is *NO* Smallpox Outbreak—

You should get the smallpox vaccine if you—

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

When There *IS* a Smallpox Outbreak—

You should get the smallpox vaccine if you—

- Are directly exposed to smallpox virus.

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

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

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

When There is *NO* Smallpox Outbreak—

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

- **Have Skin Problems**
  People with skin problems are at risk of developing rashes which can be severe if they get the smallpox vaccine.
  - Anyone who has atopic dermatitis (often called eczema) or had it in the past, should not get the smallpox vaccine.
  - Anyone who has Darier's disease (a skin disease that usually begins in childhood) should not get the smallpox vaccine.
  - Anyone who has a skin problem that has made many breaks in the skin (such as an allergic rash, bad burn, impetigo, psoriasis, pityriasis rosea, poison oak, poison ivy, chickenpox, shingles, herpes, or very bad acne) should not get the vaccine now. They should wait until the skin heals before getting the smallpox vaccine.
- **Have Immune System Problems**
  Rarely, when a person with a weakened immune system gets the smallpox vaccine, their vaccination site does not heal. Instead, it spreads to other parts of the body. This reaction can be life-threatening. Anyone with a weakened immune system should ***NOT*** get the smallpox vaccine, including anyone who:
  - Has HIV/AIDS, primary immune deficiency disorders, humoral (antibody) immunity problems (such as agammaglobulinemia or lack of normal antibodies), or other diseases that affect the immune system.
  - Has lupus or another severe autoimmune disease that weakens the immune system.
  - Has leukemia, lymphoma, or most other cancers.
  - Is taking cancer treatment with radiation or drugs, or has taken such treatment in the past 3 months.
  - Is taking, or has recently taken, drugs that affect the immune system. These include high-dose steroids (for 2 weeks or longer within the past month), some drugs for autoimmune disease, or drugs taken for an organ or bone marrow transplant.
- **Have Heart Problems**
  Smallpox vaccination may cause heart inflammation that can be mild to life-threatening. It is not known who is at risk for this problem. As a precaution, anyone who has been told by a doctor that they have a heart condition should ***NOT*** get the smallpox vaccine, even if they feel well. This includes anyone who has:
  - Known heart disease, such as past heart attack or angina (chest pain caused by lack of blood to the heart).
  - Congestive heart failure
  - Cardiomyopathy (heart muscle becomes enlarged and does not work as well as it should)
  - Stroke or transient ischemic attack (a "mini-stroke" that causes stroke-like symptoms, but no lasting damage)
  - Chest pain or shortness of breath with activity (such as walking up stairs)
  - Other heart conditions that require the care of a doctor

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

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

Are Pregnant or Breastfeeding

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

- Do ***NOT*** get the smallpox vaccine if you are pregnant, think there is a chance you are pregnant, or think you might become pregnant within 4 weeks after vaccination.
- Sexually active women are encouraged to take a pregnancy test before getting the vaccine. The test should be done the day their vaccination is scheduled. But be aware that even the best tests may not detect early pregnancies (those less than 2 weeks).
- Take steps to prevent pregnancy during the month before and the month after vaccination:
  - Do not have sex, **or**
  - Use effective birth control **every time** you have sex. Effective birth control methods include male or female sterilization, hormonal methods (such as birth control pills, implants, patches or injections) and intrauterine devices (IUDs). Condoms and the use of spermicide with diaphragms, sponges, or cervical caps are also acceptable methods, although they are less effective. Do ***NOT*** rely solely on the rhythm or 'natural family' planning method.
- Do ***NOT*** get the smallpox vaccine if you are breastfeeding. Follow this advice even if you are pumping and then bottle-feeding breast milk. It is not known if smallpox vaccine virus or antibodies can be passed to babies through breast milk.

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

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

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

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

The smallpox vaccine may pose a similar risk to them.

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

If There *IS* a Smallpox Outbreak—

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

6 WHAT SHOULD YOU EXPECT AFTER VACCINATION?

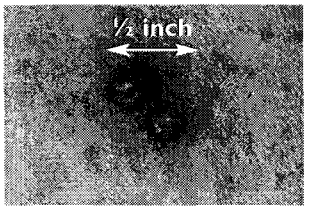
Normal Reactions

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

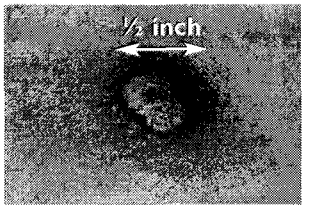
A health care provider should check your vaccination site 6–8 days after you get the vaccine to make sure the vaccination worked and everything is o.k.

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

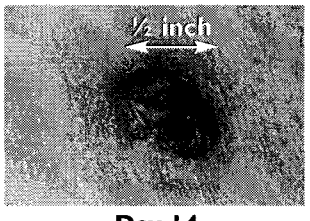
Week 3: The scab will fall off. It will leave a small scar.



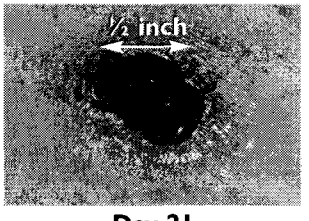
Day 4



Day 7



Day 14



Day 21

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

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

What You Will Need to Do

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

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

To Help Prevent Spread of the Virus:

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

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

7 WHAT ARE THE RISKS FROM THE SMALLPOX VACCINE?

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

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

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

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

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

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

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

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

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

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

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

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

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

What Should You Do?

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

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

Treating Serious Problems

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

Cost of Treating Serious Problems

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

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

9 HOW CAN YOU LEARN MORE?

- Ask your health care provider. They can give you more information, show you the vaccine package insert or suggest other sources of information.
  - Call your local or state health department. 1-888-767-4687
  - Visit the Centers for Disease Control and Prevention (CDC) smallpox website at **www.cdc.gov/smallpox**
  - Contact the (CDC):
    - Call **1-888-246-2675** (English)
    - Call **1-888-246-2857** (Español)
    - Call **1-866-874-2646** (TTY)

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

To allow medical care provider(s) accurate immunization status information, an immunization assessment, and a recommended schedule for future immunizations, information will be sent to the Michigan Care Improvement Registry. Individuals have the right to request that their medical care provider not forward immunization information to the Registry.

DCH-1216 AUTH: P.H.S., Act 42, Sect. 2126.