



## Questions and Answers about Autoimmunity and the Smallpox Vaccine

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### 1. What is the risk of developing smallpox?

Smallpox does not exist as a naturally occurring disease anywhere in the world. The only risk of smallpox would come from the use of smallpox as a weapon of bioterrorism. Government security experts believe that bioterrorists in several countries may have possession of the virus. No one knows for certain whether or not they do possess smallpox or if smallpox will be used as a weapon. Most infectious disease experts believe that the risk of any individual being exposed to smallpox is extremely low.

### 2. How good is this vaccine?

No vaccine is perfect. The smallpox vaccine provides approximately 95% protection against smallpox. This is about as effective as most other live viral vaccines.

### 3. What kinds of adverse reactions can occur?

Smallpox vaccine causes a local infection on the arm. A small group of blisters or vesicles develop associated with inflammation, swelling and tenderness that last for 1–2 weeks. About 10% of people develop an exaggerated reaction with more marked swelling, redness and tenderness and decreased use of the arm for a few days. Some people develop red streaks going around the arm that resolve spontaneously, but this reaction is sometimes mistakenly assumed to be a secondary bacterial infection. Headache, fever, and feeling poorly for a few days occur frequently. About one-third of healthy young adults who were vaccinated reported missing at least one day of work, school, or participating in usual activities. More serious reactions occur much less commonly.

The vaccine virus can be transmitted from the vaccination site to some other part of the body or to people who have direct contact with a vaccinated person. The virus is transmitted on hands after touching the vaccine site. There is no evidence that the virus is transmitted through respiratory droplets or that there is any risk from being in the same room as a vaccinated person. If the vaccine virus is put on an area where the skin is broken or on a mucous membrane such as the mouth, eye, vagina, or rectum, then sores develop that are similar to the sore at the vaccination site. This can create serious problems if the virus is placed in or around the eye or the genital area. The vaccine is not recommended for anybody with acute or chronic skin conditions that could predispose to this problem. People with eczema are at a particular high risk of

developing severe reactions. Any person with eczema, atopic dermatitis, or any household member who has these conditions should not be vaccinated.

When smallpox vaccine was given to pregnant women, the vaccine virus was sometimes transmitted to their unborn babies and caused serious infections and sometimes premature birth. When the vaccine was given to children under 1 year of age they had a higher risk of developing encephalitis than older children and adults. The risk in adults is about 1–2 per million and this complication can lead to long-term brain damage or death.

### 4. Are there special risks for patients with immune disorders?

Yes, patients with immune deficiency disorders and their household contacts should not be vaccinated. Persons with defects in lymphocyte function, including people with leukemia and other forms of cancer, are at high risk of developing a serious and frequently fatal complication called progressive vaccinia. Although patients with mild defects in the immune system that do not affect lymphocyte function may not be at increased risk, there is no reason for these people to be vaccinated at this time. If there were to be outbreaks of smallpox associated with bioterrorism, these people should check with their doctors before considering smallpox vaccination.

### 5. I am being treated with prednisone. Should I take the vaccine?

Any person with a condition that requires the use of prednisone or other immunosuppressive agents should not receive smallpox vaccine at this time. Although low doses of prednisone do not usually cause any problems with live viral vaccines, these persons might require higher doses of prednisone if their underlying condition becomes more severe, and we do not have any data on what doses of prednisone might be safe for people who receive smallpox vaccine.

### 6. If I have an autoimmune disease, should members of my family take the vaccine?

If you have an autoimmune disease that might require the use of steroids or other therapy that could affect the immune system, no one in your family who lives in the same household should receive smallpox vaccine because you might acquire the smallpox vaccine virus from your family member.

**7. If I have an autoimmune disease, should I stay away from my place of employment if there are people there who have been vaccinated? If so, how long should I stay away?**

You do not need to stay away from your place of work where people have received smallpox vaccine. We do not have the same physical contact with people in the workplace that we have with family members. Vaccinated individuals in the workplace should have their smallpox vaccine site covered with special bandages that will markedly reduce, if not eliminate, the risk of them transmitting the virus to you. If vaccinated people take appropriate precautions with regard to care of the vaccine site, then they can continue to shake hands and have other minimal contact with other persons.

**8. Are there any special precautions that I as an autoimmune disease patient should take if there is a national vaccination program?**

If your disorder puts you at increased risk, you should take care to minimize direct touching contact with people who may have received smallpox vaccine and who have an open sore that could contain the virus. If your job requires direct physical contact with people, such as people who do massage therapy, then you might consider asking clients who have been vaccinated not to come for therapy during the time that they have an open sore from the vaccine.

**9. If I have an autoimmune disease that affects the skin, should I take the vaccine?**

If you have active lesions from psoriasis, cutaneous vasculitis, bullous pemphigoid, Behçet's disease, discoid lupus, Mooren's ulcer or any other skin disorder, you should not receive the vaccine. If your skin disorder is under control and you do not have any open lesions, and the vaccine is highly recommended for you because of your occupation, then you might consider receiving the vaccine after consultation with your physician. If it is not essential for you to be immunized, then we would advise against it.

**10. Is there any way of treating the adverse reactions if they occur?**

Some adverse reactions can be treated with a special immune globulin preparation that appears to help patients with eczema vaccinatum, severe inoculation around the eye or other sites, and possibly for progressive vaccinia. There is one antiviral drug that is available for investigational purposes, but it has a high rate of

serious side effects. These drugs are available through the Centers for Disease Control and Prevention.

**11. Is there a safer vaccine available for patients with autoimmune disease?**

A new smallpox vaccine is currently being tested and should become available sometime during 2003. This vaccine is made from the same virus present in the current smallpox vaccine. The new vaccine will be grown in cell culture rather than on the calf skin. Since the virus is the same, the new vaccine will probably have the same risk of adverse reactions as the current vaccine. Scientists are working on developing safer vaccines against smallpox, but it will take at least 5–10 years before these vaccines might become available.

**12. Is the situation likely to change with regard to the risk of exposure to smallpox?**

Almost all infectious disease experts recommend against routine vaccination of the civilian population because the risks of exposure to smallpox are very small and probably close to zero. Experts are constantly reevaluating the potential for exposure from bioterrorism. As the United Nations investigations in Iraq continue, we should learn whether or not this country has produced smallpox for possible use as a weapon. If there was one small event in a single location, this may not change the equation with regard to balancing the risks and benefits from this vaccine for the general population. Experts would contact everyone who had been exposed to be sure that they were immunized, but it would not require immunization of the general population. Smallpox vaccine can protect against smallpox even when it is administered up to 4 days after exposure. If someone has a known exposure to smallpox, then there are very few contraindications to using the vaccine and people with skin disorders and mild immune deficiency disorders would be immunized. If there was a confirmed large outbreak in your local community, then many experts believe that almost everyone in that community should receive the vaccine. We must always weigh the potential benefits of vaccines against the potential risks. At this time smallpox vaccination is not warranted for the general public.

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