

Questions and Answers: Smallpox and Smallpox Vaccine

Q1: What is the IDF's position on the Federal government's current Smallpox vaccination plan?

A1: IDF agrees with the Federal government's characterization of bioterrorism as a "clear and present danger," and, therefore, we support the goal of providing safeguards against bioterrorism, including the use of Smallpox vaccination strategies. However, because the Smallpox vaccine is a **live virus vaccine**, it is possible that some individuals with primary immune deficiency diseases exposed to the virus--either through direct vaccination or through contact with a vaccinated individual--could suffer significant complications and in some cases death. For this reason, we are urging government authorities to include a few simple public health measures in the current comprehensive working plan already in place to further minimize potential adverse consequences for our patient population.

Q2: What are those additional public health measures?

A2: Specifically, IDF believes the following issues should be addressed immediately in the interest of providing adequate protection to primary immune deficient patients:

1. Implementation of a questionnaire at vaccination locations to identify undiagnosed primary immune deficient individuals; and
2. Development and implementation of a clear public health message that both the vaccine AND vaccinated individuals pose risks to certain individuals by:
 - o Communication of simple instructions to recently vaccinated individuals informing them of the potential for the virus to spread to others; and
 - o Communication to the general public regarding these risks.

Q3: What is Smallpox?

A3: Smallpox is a very serious infectious disease caused by the *variola* virus. The incubation period following exposure to the virus is, on average, 12-14 days. Initial symptoms of infection include high fever, fatigue, head and backaches. A characteristic rash appears most prominently on the face, arms and legs 2-3 days after initial symptoms. The lesions become pus-filled and form scabs, which fall off after 3-4 weeks. While the majority of individuals with Smallpox recover, death can occur in up to 30% of cases.

Q4: Why are we currently concerned about Smallpox?

A4: The last reported case of Smallpox infection in the world was in 1977. Routine vaccination against Smallpox in the general public was stopped because it was no longer necessary for prevention. After Smallpox was declared to be eliminated from the world in 1979, a decision was made that any remaining stocks of the virus were required to be stored in two laboratories, one in the United States and one in Russia. Some governments, such as the U.S. Government, believe that the Smallpox virus may exist in other places besides these two laboratories and could be deliberately released to cause harm.

Q5: How is Smallpox transmitted from person to person?

A5: The virus that causes Smallpox is contagious and spreads through person-to-person contact, contaminated clothing and bedding, and saliva droplets from an infected person. In a theoretical attack with biological weapons, exposure to Smallpox could also occur by breathing the airborne virus. A person with Smallpox infection is contagious after a rash appears and remains contagious until the last Smallpox scab falls off.

Q6: What is the Smallpox vaccine?

A6: The Smallpox vaccine is a **live virus vaccine**. It is made from a virus called *vaccinia*, which is another “pox”-type virus related to Smallpox. While vaccination with vaccinia virus helps protect the body from developing Smallpox infection, some individuals will have side effects and serious complications from the vaccine because it contains the live vaccinia virus.

Q7: Who is at risk of developing complications from the Smallpox vaccine?

A7: Because the Smallpox vaccine is a live virus, anyone receiving the vaccine is at some risk for developing side effects or more serious complications from it. However, individuals who are at highest risk of developing complications from the Smallpox vaccine include:

- People with weakened immune systems due to **primary immune deficiency diseases**, HIV infection, certain cancers, or immunosuppressive agents used to treat cancer or organ transplantation
- People who have now, or have ever had skin conditions such as atopic dermatitis or eczema
- Pregnant women

Q8: What are the potential complications of the Smallpox vaccine in individuals with primary immune deficiency diseases or other high-risk medical conditions?

A8: Potential side effects of the Smallpox vaccine in normal individuals include development of a rash, fever, and head and body aches. The CDC reports that in the past, about 1,000 people for every million vaccinated experienced non life-threatening reactions. More serious and potentially fatal complications that can occur from receiving the Smallpox vaccine include: *postvaccinal encephalitis, progressive vaccinia infection, and eczema vaccinatum*. The CDC reports that in the past, between 14-52 people per million vaccinated experienced these potentially life-threatening reactions.

In the past, *progressive vaccinia* as a complication of Smallpox vaccination was a fatal complication among some individuals with cell-mediated immune deficiency disease. Progressive vaccinia results from the failure of the vaccinia lesion to heal and leads to the progression of the infection to other parts of the skin, bones and other organs.

Q9: Who should NOT receive the Smallpox vaccine?

A9: In the absence of a Smallpox outbreak, the CDC does not recommend the Smallpox vaccine for the following groups of individuals:

- People with weakened immune systems due to **primary immune deficiency diseases**, HIV infection, certain cancers or immunosuppressive agents used to treat cancer or organ transplantation

- People who have now, or have ever had skin conditions, such as atopic dermatitis or eczema
- Pregnant women
- People in close contact with individuals who fall into any of these groups, such as family members

Q10: Why is there a risk to individuals with primary immune deficiency disorders if a close contact is vaccinated?

A10: The Smallpox vaccination site forms a pustule which scabs over after 3 weeks. Exposure to this site or to the shedding scab during this time period could result in spreading of the virus to an unvaccinated individual. This is called contact vaccinia and can lead to the complications, mentioned in Answer #8, in the unvaccinated individual.

Q11: How can you reduce your risk of contacting vaccinia from the Smallpox vaccine?

A11: To reduce the risk of contacting vaccinia, the Smallpox vaccine is not recommended for close contacts of individuals in any of the high-risk groups mentioned in Answer #9, in the absence of a Smallpox outbreak. It is recommended that unvaccinated individuals avoid close contact with vaccinated individuals during the contagious period, which can be up to 3 weeks after the vaccination. Close contact includes touching a vaccinated individual or exposure to the clothing or bedding of a vaccinated individual. In some circumstances, isolation of the unvaccinated person may be prudent.

Additionally, to help reduce the risk of contact vaccinia, the Centers for Disease Control and Prevention (CDC) recommend the following guidelines for care of the Smallpox vaccination site in vaccinated individuals: covering the vaccination site with absorbent gauze and then with a layer of semi-permeable dressing to provide a barrier to the virus; thorough hand washing hygiene after any contact with the bandage or vaccination site.

Q12: How do you evaluate the risk of vaccine complications for you or your family member?

A12: The Smallpox vaccine is not recommended for individuals with primary immune deficiency disorders and/or any of the above listed medical conditions in the absence of a Smallpox outbreak. It is best to consult with an Immunologist when evaluating the risk of complications for you or your family member.

Q13: Is treatment available for individuals who develop complications from the Smallpox vaccine?

A13: Yes. Vaccinia immune globulin (VIG) is a concentrated antibody preparation that is used to treat complications from the Smallpox vaccine. However, the CDC states that due to an extremely limited supply, VIG should be reserved for treatment of the most serious or life threatening complications.

Q14: When Smallpox vaccinations are initiated, how can I find out what is being done nationally and in my local community?

A14: The U.S. government is currently developing recommendations for Smallpox vaccinations to be given to 500,000 first responders. These individuals would include health care workers and other professionals most likely to respond first in the event of a Smallpox outbreak. By 2004, an additional 10-15 million health care workers and the general public may participate in voluntary Smallpox vaccination. Because individuals with primary immune deficiency diseases may come in contact with vaccinated individuals and be at risk for contact vaccinia, it is important for you to know what is happening in your local community. For more information about the Smallpox vaccination plan, please contact the Centers for Disease Control Public Response Hotline at (888) 246-2675 or via the Internet at www.bt.cdc.gov/agent/Smallpox/index.asp. For information about implementation of the Smallpox vaccination plan in your community, contact your state or local health department.

Q15: Where can I find more information?

A15: Please utilize the following websites:

- Centers for Disease Control and Prevention: www.cdc.gov; or at the above hotline.
- Immune Deficiency Foundation: www.primaryimmune.org
- Clinical Focus on Primary Immune Deficiency Diseases: Immunization of the Immunocompromised Host: www.primaryimmune.org . Go to “Literature” and then to “Clinical Focus”. It is the October 1998 issue.

References

1. Centers for Disease Control and Prevention. *Smallpox Overview; Information on Live Virus Vaccines and Vaccinia; Smallpox Vaccine Overview; Smallpox Vaccination and Adverse Events Training Manual; Summary of October 2002 ACIP Smallpox Vaccination Recommendations*. Available at www.bt.cdc.gov/agent/Smallpox/index.asp. Accessed October 30, 2002.
2. Henderson DA, Inglesby TV, Bartlett JG, Ascher MS, Eitzen E, Jahrling PB, Hauer J, Layton M, McDade J, Osterholm MT, O'toole T, Parger G, Perl T, Russell PK, Tonat K. Smallpox as a Biological Weapon: Medical and Public Health Management. *JAMA*. 1999; Vol. 281, No. 22: 2127-2137.
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