

## ***Smallpox Vaccine in Pregnancy Registry***

### **INFORMATION PAPER: When Pregnancy Is Discovered After Smallpox Vaccination**

**1. Purpose.** This paper provides information for women who discover they are pregnant after receiving smallpox vaccination.

#### **2. Current Recommendations on Vaccination and Pregnancy**

Similar to other live virus vaccines, smallpox vaccine is not recommended for pregnant women in non-emergency situations. Further, it is recommended that women who receive the vaccine should avoid becoming pregnant for at least 4 weeks after vaccination.

Because it can be difficult to predict conception or diagnose early pregnancy, it is not surprising that some women may inadvertently receive smallpox vaccine shortly before or after becoming pregnant.

#### **3. Historic Experience with Smallpox Vaccine in Pregnancy**

Smallpox vaccine recommendations have changed over time. In the mid-20<sup>th</sup> century, when smallpox disease was still naturally occurring, billions of women around the world, both pregnant and not pregnant, received the vaccine. During smallpox outbreaks, health officials intentionally gave pregnant women smallpox vaccine to protect them from lethal infections.

There is no historic evidence that smallpox vaccine caused increased rates of spontaneous abortion (miscarriage). There is no historic evidence that the smallpox vaccine used in the United States caused birth defects.

Fetal vaccinia is a known, but extremely rare, complication that can occur after smallpox vaccine is given in pregnancy. Fetal vaccinia occurs when the virus used in smallpox vaccine infects the unborn baby (fetus). Cases of fetal vaccinia have been associated with stillbirth or infant death shortly after delivery. In the 20<sup>th</sup> century, 3 cases of fetal vaccinia were reported in the United States, and 47 cases were reported from other countries around the world. It is possible that other cases occurred, but were not reported. No cases of fetal vaccinia were reported after 173,000 pregnant women in New York City were vaccinated in 1947. It is estimated that 1 case of fetal vaccinia might occur for every 10,000 to 100,000 pregnant women who get smallpox vaccine for the first time.

#### **4. Recent Experience with Smallpox Vaccine in Pregnancy**

The Smallpox Vaccine in Pregnancy Registry, established in 2003 and managed by the Department of Defense Birth and Infant Health Registry, follows women who inadvertently receive smallpox vaccine while pregnant. The Registry collects confidential information to better understand if smallpox vaccine in pregnancy is associated with problems for mothers or infants in the modern era.

In the United States, approximately 17% of all recognized pregnancies end in miscarriage, and 3% to 5% of infants are born with birth defects. It is natural for parents who suffer a pregnancy loss, or have a baby with a birth defect, to want to know the cause. Unfortunately, the causes of most miscarriages and birth defects are unknown.

Thus far, information from the Smallpox Vaccine in Pregnancy Registry indicates that miscarriages and birth defects occur at rates similar to, or less than, rates seen in the general population. Women who inadvertently receive smallpox vaccine while pregnant may be reassured that current data support historic data, and do not suggest that they are at higher risk for pregnancy loss or giving birth to a child with a birth defect.

In addition, there have been no cases of fetal vaccinia among pregnancies followed by the Registry.

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### **5. Better Understanding Pregnancy Losses**

It may be possible to know if smallpox vaccine was associated with a miscarriage or stillbirth by laboratory testing for vaccinia virus. In order to perform this testing, specimens must be brought to a special laboratory and preserved (without formalin) at –70C in viral transport media. Women who would like to have this testing performed should discuss with their healthcare providers as soon as possible after a miscarriage is diagnosed.

### **6. Resources for Additional Information**

The Smallpox Vaccine in Pregnancy Registry was established to collect important confidential information from women who received smallpox vaccine in pregnancy. Professionals from the Registry can answer many questions from participants and their healthcare providers. The Registry may be contacted at:

National Smallpox Vaccine in Pregnancy Registry  
c/o DoD Birth and Infant Health Registry,  
NHRC Dept 164, 140 Sylvester Road, San Diego, CA 92106  
Phone: 619-553-9255 (DSN 553-9255)  
Fax: 619-553-7601  
Email: NHRC-BirthRegistry@med.navy.mil

Additional resources include:

Vaccine Healthcare Center Network  
c/o Walter Reed Army Medical Center, Washington, DC  
Phone: 202-782-0411 (DSN 662)

Military Vaccine (MILVAX) Agency  
Falls Church, VA  
Phone: 877-GET-VACC or 703-681-5101 (DSN 761)

Department of Obstetrics and Gynecology, Division of Maternal-Fetal Medicine  
Madigan Army Medical Center, Tacoma, WA  
Phone: 253-968-1710 or 1252 (DSN 782)

### **References**

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CDC. Recommendations for Using Smallpox Vaccine in a Pre-Event Vaccination Program. MMWR 2003;52(RR07):1-16. <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5207a1.htm>

Levine MM, Edsall G, Bruce-Chwatt LJ. Live-virus vaccines in pregnancy: Risks and recommendations. Lancet 1974;2:34-8.

Naderi S. Smallpox vaccination during pregnancy. Obstet Gynecol 1975;46(2):223-6. (Note that the vaccine strain described here and used in Iran was different from the vaccine used in the United States.)

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