

**SMALLPOX FACT SHEET****Smallpox Vaccination Information for Women Who Are Pregnant or Breastfeeding****What is smallpox vaccine?**

The smallpox vaccine helps the body develop immunity to smallpox. The vaccine is made from a virus called vaccinia which is a "pox"-type virus related to smallpox. The smallpox vaccine contains the "live" vaccinia virus—other vaccines containing live virus include measles, mumps, and German measles. For that reason, the vaccination site must be cared for carefully to prevent the virus from spreading. Also, the vaccine can have side effects. The vaccine does not contain the smallpox virus and cannot give you smallpox.

Pregnancy**Should pregnant women receive the smallpox vaccine?**

No. Women who are pregnant or planning to become pregnant within 4 weeks after vaccination should NOT get the smallpox vaccine. In addition, anyone who has a close contact who is pregnant should not get the vaccine (close contacts include anyone living in your household and anyone you have close, physical contact with such as a sex partner or someone you share a bed with). The smallpox vaccine is a live viral vaccine that is made from a virus called vaccinia. Live virus vaccines are generally not recommended during pregnancy. Pregnant women should not get the smallpox vaccine unless they have been in contact with someone with smallpox disease. The vaccine can cause a very rare but serious complication in the fetus called fetal vaccinia (less than 50 cases of fetal vaccinia have ever occurred). However, most babies born after smallpox vaccine exposure will be fine.

If a woman is vaccinated she should prevent pregnancy for a month. She should wait until the vaccination site has completely healed and the scab has fallen off before trying to become pregnant after vaccination. Until that time, effective measures should be taken to prevent pregnancy, such as birth control pills, injections, implants, IUDs, or abstinence. Other methods of birth control, such as condoms, diaphragms, spermicide, and natural family planning are less effective.

Is it safe for pregnant women to have contact with a person who has recently received the smallpox vaccine?

Women who are pregnant should not have close contact with anyone who has recently (within the last 28 days) received the smallpox vaccine. A close contact includes anyone living in your household and anyone you have close, physical contact with (such as a sex partner or someone you share a bed with). Other friends or people you work with are not considered close contacts.

What if my obstetrician has been vaccinated?

The close contact required for transmission of vaccinia infection to close contacts is not likely to occur in the healthcare setting. Healthcare workers who have received smallpox vaccine are taking precautions to practice strict vaccination site care and hand hygiene, so that their patients will not come into contact with the vaccination site, or with any materials that have come into contact with the vaccination site.

SMALLPOX FACT SHEET: Smallpox Vaccination Information for Women Who Are Pregnant or Breastfeeding

(continued from previous page)

If pregnant women are vaccinated with the smallpox vaccine are there any special risks to the fetus?

In pregnant women, smallpox vaccination can cause a very rare but serious complication called fetal vaccinia. Fetal vaccinia is an infection in the unborn baby that can lead to premature delivery, skin rash with scarring, stillbirth, or death of the baby after delivery. Sometimes a baby who develops fetal vaccinia is born with skin scars but is otherwise healthy. Fewer than 50 cases of fetal vaccinia have ever been reported in the world, and only three of these cases were reported in the United States. When smallpox vaccine was routinely given in the United States from 1967 to 1971, only one case of fetal vaccinia occurred among an estimated 90,000 to 280,000 pregnant women who received the vaccine. It is estimated that 5,700 to 17,000 of these pregnant women were receiving the vaccine for the first time. Therefore, although the risk to the unborn baby is known to exist, that risk is low and fetal vaccinia is very rare.

Are babies born to pregnant women who have received smallpox vaccine at increased risk for birth defects?

Smallpox vaccine has not been shown to cause an increased risk of serious birth defects.

Are pregnant women who receive the smallpox vaccine more likely than other pregnant women to have a miscarriage?

Smallpox vaccine has not been clearly associated with an increased risk of miscarriage. More research needs to be done to better answer this question.

Are there any other special risks after birth for children who are born to mothers who received smallpox vaccine during pregnancy?

Except for the rare case of fetal vaccinia, smallpox vaccination of pregnant women has not been linked with prematurity, low birth weight, or other serious birth problems. Babies born without fetal vaccinia are not known to have a greater risk of future medical problems.

Should pregnant women who receive the smallpox vaccine undergo any special medical tests?

There is no known test that can reliably confirm before birth if a baby is infected with vaccinia. Pregnant women who have received the smallpox vaccine should receive regular prenatal care, and should discuss their smallpox vaccination with their healthcare provider. There are tests that are being studied in a research setting to confirm infection after birth, and these might prove helpful in the future. These tests involve taking a sample of blood from the umbilical cord after the baby is born and testing for the presence of vaccinia virus or antibodies (substances that help fight off infection) against the virus. Likewise, if a pregnancy ends in miscarriage or termination the tissue from the fetus may be tested for the smallpox vaccine virus.

Is smallpox vaccination or close contact with a recently vaccinated person during pregnancy a reason to consider pregnancy termination?

There have been less than 50 cases of fetal vaccinia ever reported in the world. Because fetal vaccinia is so rare, smallpox vaccination during pregnancy should not be a reason to consider termination of pregnancy.

Are there special considerations at the time of delivery for women exposed to smallpox vaccine during pregnancy?

Most women who receive smallpox vaccine during pregnancy will deliver normal babies, and standard delivery procedures should be followed. All pregnant women who have received the smallpox vaccine during pregnancy should let their healthcare provider and their baby's healthcare provider know about their vaccination.

May 6, 2003

Page 2 of 5

SMALLPOX FACT SHEET: Smallpox Vaccination Information for Women Who Are Pregnant or Breastfeeding

(continued from previous page)

Are there special considerations for pregnant women who have a “robust” reaction after smallpox vaccine?

Sometimes, especially among first-time vaccinees, the smallpox vaccination reaction is unusually large and painful. This is called a robust take. Robust takes usually get better on their own in a few days, and only require rest and observation. Pregnant women should not receive the smallpox vaccine. However, if a pregnant woman is vaccinated, she should check with her healthcare provider for further information if she has a robust take and before taking any medication during pregnancy. There are no additional considerations for pregnant women who have a robust reaction.

If a pregnant woman who has received smallpox vaccine develops a serious reaction what should she do?

Anyone who thinks they are having a serious reaction to the smallpox vaccine should either call the phone number provided on the “Post-Vaccination and Follow-Up Information Sheet” given to them at the time of vaccination, call their healthcare provider, or visit an emergency room.

Should pregnant women who have received the smallpox vaccine receive Vaccinia Immune Globulin (VIG)?

Vaccinia Immune Globulin (VIG) is a treatment that can be used to help people who have certain serious reactions to smallpox vaccine. VIG is made from the blood of people who have gotten the smallpox vaccine more than once. It contains substances (antibodies) that give protection from vaccinia infection. Women should contact their healthcare provider regarding use of VIG. Currently, CDC’s Advisory Committee on Immunization Practices does not recommend preventive use of Vaccinia Immune Globulin (VIG) for pregnant women. However, if a woman has another complication from smallpox vaccine that could be treated with VIG, it is ok for her to receive it while she is pregnant.

If a woman wants to get pregnant, how long does she need to wait after receiving the smallpox vaccine?

A woman should wait until the vaccine site has completely healed and the scab has fallen off before trying to become pregnant after vaccination. Generally, this means women who have received the smallpox vaccine should wait at least four weeks (28 days) before becoming pregnant. Until that time, effective measures should be taken to prevent pregnancy, such as birth control pills, injections, implants, IUDs, or abstinence. Other methods of birth control, such as condoms, diaphragms, spermicide, and natural family planning are less effective.

If a woman wants to get pregnant, how long does she need to wait if a close contact has received the smallpox vaccine?

A close contact includes anyone living in your household and anyone you have close, physical contact with (such as a sex partner). A woman should wait until the vaccine site in her close contact has completely healed and the scab has fallen off before trying to become pregnant after vaccination. Generally, this means a woman should wait at least four weeks (28 days) after close contact with a vaccinated person before becoming pregnant. Until that time, effective measures should be taken to prevent pregnancy, such as birth control pills, injections, implants, IUDs, or abstinence. Other methods of birth control, such as condoms, diaphragms, spermicide, and natural family planning are less effective.

Should a woman of child-bearing age get a pregnancy test before receiving a smallpox vaccine?

Any woman who thinks she could be pregnant should perform a pregnancy test, by using her first morning urine, on the day vaccination is scheduled. However, even the most sensitive tests may not be able to detect early pregnancies (those less than two weeks along). Thus, if a woman thinks she might be pregnant, she should not get the smallpox vaccine.

SMALLPOX FACT SHEET: Smallpox Vaccination Information for Women Who Are Pregnant or Breastfeeding

(continued from previous page)

If the pregnancy test is negative can a woman still be pregnant?

Yes. A urine pregnancy test may not be able to detect a very early pregnancy. In addition, sometimes a test performed on dilute (watered-down) urine may not be able to detect a pregnancy.

At what time of the month is a woman least likely to be pregnant?

A woman is least likely to be pregnant during the early days of her menstrual period.

What is being done to learn more about how to prevent pregnant women from being exposed to smallpox vaccine and what happens to their babies if pregnant women are exposed?

CDC, together with state health departments and the Food and Drug Administration (www.fda.gov/), is conducting a public health response to learn how some women received the smallpox vaccine while they were pregnant or just before they became pregnant. This is being done in order to help prevent pregnant women from being exposed to smallpox vaccine in the future. CDC has also established the National Smallpox Vaccine in Pregnancy Registry. This registry will follow women during their pregnancies and their babies, after they are born, to better understand what happens to pregnant women and their babies who have been exposed to smallpox vaccine.

How do I sign up for the Registry if I have received the smallpox vaccine?

Pregnant women who have received the smallpox vaccine, or pregnant women whose close contacts have received the smallpox vaccine, may contact their healthcare provider or their state health department for help in enrolling in the registry. Health-care providers and staff from state health departments (see www.cdc.gov/other.htm#states) are encouraged to report all exposed pregnant women to the registry by calling 404-639-8253.

If there were ever a case of smallpox, would pregnant women be vaccinated?

If there is a smallpox outbreak, recommendations on who should get vaccinated will change. Anyone who is exposed to smallpox should get vaccinated, because they will be at greater risk from the disease than they are from the vaccine. Public health authorities will recommend who should be vaccinated at that time and what measures people can take to protect themselves from smallpox.

Breastfeeding

Is smallpox vaccine safe for women who are breastfeeding?

Women who are breastfeeding should not get the vaccine. This advice is true even if women are pumping and then bottle-feeding breast milk. It is unknown whether the vaccine virus or antibodies pass on to the baby through breast milk.

Is it safe for women who received smallpox vaccine during pregnancy to breastfeed their babies?

Pregnant women should not receive the smallpox vaccine unless they have been exposed to smallpox. If a pregnant woman is vaccinated or if a woman becomes pregnant after vaccination, breastfeeding should not take place until the vaccination scab has separated from the vaccination site.

If a woman who is breastfeeding receives the smallpox vaccine should she stop nursing?

Yes. Breastfeeding should not take place until the vaccination scab has separated from the vaccination site. A woman who desires to maintain her milk supply may continue to pump breast milk, but the milk should be discarded until her scab fully separates.

SMALLPOX FACT SHEET: Smallpox Vaccination Information for Women Who Are Pregnant or Breastfeeding

(continued from previous page)

Is it safe for a woman to breastfeed her baby if a close contact received the smallpox vaccine?

Yes. However, anyone who receives the smallpox vaccine should remember to wash their hands with soap and warm water after direct contact with the vaccination site, or anything that has touched the vaccination site (bandages, clothing, towels, bedding, etc.). This will help prevent the spread of vaccinia virus to contacts, including young babies.

If a breastfeeding mother who has close contact with a recently vaccinated person develops a rash, should she stop nursing?

If a breastfeeding mother who has had close contact with a person recently vaccinated against smallpox develops a rash, she should check with her healthcare provider to determine if the rash is related to the smallpox vaccine. If she has a vaccine-related rash, breastfeeding should not take place until all scabs from the rash have fallen off. A woman who desires to maintain her milk supply may continue to pump breast milk, but the milk should be discarded until her scabs fully separate.

If there were ever a case of smallpox, would breastfeeding women be vaccinated?

If there is a smallpox outbreak, recommendations on who should get vaccinated will change. Anyone who is exposed to smallpox should get vaccinated, because they will be at greater risk from the disease than they are from the vaccine. Public health authorities will recommend who should be vaccinated at that time and what measures people can take to protect themselves from smallpox.

For more information, visit www.cdc.gov/smallpox, or call CDC at 800-CDC-INFO (English and Spanish) or 888-232-6348 (TTY).

May 6, 2003

Page 5 of 5