Attachment K. Counseling messages for study participants

What is Zika virus Infection?

Zika virus infection is an infection caused by the Zika virus and is most often transmitted to people through mosquito bites, though sexual transmission has also been documented. Most people who are infected with Zika virus never have any symptoms at all. About 1 in 5 people infected with Zika virus experience mild illness and the most common symptoms include fever, joint pains, rash, or conjunctivitis (red eye). These symptoms typically resolve on their own within a week. There are reports out of Brazil, which has a large number of Zika virus infection cases, that children born to women who have a Zika infection during their pregnancy have a higher risk of a condition called microcephaly: a birth defect in which the head and/or brain of the baby does not develop normally. The connection between Zika virus infection and microcephaly is not well understood. Zika virus infection in a mother does not definitely mean a child will develop microcephaly. However pregnant women who have had a Zika infection should be monitored more closely throughout their pregnancy in accordance with CDC guidance

(http://www.cdc.gov/mmwr/volumes/65/wr/mm6502e1.htm).

What does it mean if the samples from body fluids test positive for Zika virus RNA?

If you have a positive test, it means that we found fragments of the virus (RNA) in your blood, saliva, urine or semen/vaginal secretions. We will tell you in which sample we found the fragments of the virus and for how long the virus can be found in your sample. There is a very small chance that this test can give a positive result that is wrong; this is called a false positive result.

If you find RNA in my samples how to I prevent passing Zika to others?

During the first week of infection, Zika virus can be found in the blood and passed from an infected person to another mosquito through mosquito bites. An infected mosquito can then spread the virus to other people. To help prevent others from getting sick, avoid mosquito bites (see below) during the first week of illness.

There is evidence that the Zika virus can be sexually transmitted by a man to his sex partners. We do not know if women can transmit Zika to her sex partners. If we find fragments of the Zika virus in your semen or vaginal secretions you should use a condom correctly every time you have sex. We do not know for how long the virus will remain in semen or vaginal secretions.

If you find RNA in my semen and my partner is trying to get pregnant or thinking about getting pregnant, how long do we need to wait before trying to get pregnant?

We do not know how long the Zika virus is present in semen for men who have been infected with Zika. One report found the virus in semen at least two weeks after illness. No follow up testing was done to determine when the man no longer had Zika virus in his semen. At this time, we do not know how long the Zika virus can be sexually transmitted from a male partner. We will tell you the results of the testing in your semen and when we are no longer finding it. We do not know how long after finding RNA in your semen it is safe to get pregnant.

If you find RNA in my body fluids and I am interested in getting pregnant, how long do I need to wait before trying to get pregnant?

Zika virus can be passed from a mother to her fetus during pregnancy. If we find Zika virus fragments in any of your body fluids you should avoid getting pregnant by using condoms correctly every time you have sex or abstaining form sex. Currently, there is no evidence to suggest that Zika virus, after it is cleared from the body, poses a risk of birth defects for future pregnancies. Zika virus usually remains in the blood of an infected person for about a week and in other fluids such as urine for up to 30 days.

If I am pregnant and test positive for Zika virus, does it mean that my child will have microcephaly?

Not necessarily. This test can only give doctors information about your health, not the health of your child. While this test result may lead your doctors to monitor your pregnancy more closely, a Zika virus infection in a mother does not mean there is definite harm to the child.

What does it mean if the samples from body fluids test negative for Zika virus RNA?

A negative test for Zika virus in your body fluid samples presumes that Zika virus RNA was not present in the specimen at the detection level of the assay. However, negative results do not rule out Zika virus infection and should not be used as the sole basis for treatment or other patient management decisions.

How to prevent Zika?

No vaccine exists to prevent Zika. Prevent Zika by avoiding mosquito bites. Mosquitoes that spread Zika virus bite mostly during the daytime. Mosquitoes that spread Zika virus also spread dengue and chikungunya viruses. Some of the ways to prevent Zika virus or other viruses spread by mosquitoes are:

- Wear long-sleeved shirts and long pants.
- Stay in places with air conditioning or that use window and door screens to keep mosquitoes outside.
- Sleep under a mosquito bed net
- Use Environmental Protection Agency (EPA)-registered insect repellents. When used as directed, EPA-registered insect repellents are proven safe and effective, even for pregnant and breast-feeding women. Do not use insect repellent on babies younger than 2 months of age.

Treat clothing and gear with permethrin or purchase permethrin-treated items.