

Wednesday, August 18, 2004 02:54 PM

Dear Colleagues,

Thank you for your interest in the question of adverse birth effects of West Nile virus (WNV) infections during pregnancy, and in CDC's voluntary registry.

In 2003, cooperation between CDC, state health officials, and health care providers resulted in the nationwide registration of 74 women with WNV infections during pregnancy. Complete birth outcome data for this cohort are still being accumulated and analyzed. The consequences of WNV infections during pregnancy remain unclear. In 2004, your continued assistance in registering WNV-infected pregnant women would be appreciated.

The following is some background on this registry:

In 2002, CDC and the New York State Department of Health reported a case of human intrauterine West Nile virus (WNV) infection in an infant with severe congenital abnormalities <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5150a3.htm>. That year, there were three additional instances of pregnancy-associated WNV disease cases with no laboratory evidence of intrauterine WNV infection, and in all three cases, the infants were born apparently normal.

In 2003, CDC and state health departments organized a surveillance registry and gathered data on pregnancy outcomes for 74 women infected with WNV disease in pregnancy. Of the 74 women, two had electively aborted amid concerns of possible teratogenic effects of WNV; five miscarried in the first trimester; and 67 gave birth to live infants. Among the 68 live-born infants (one woman had twins) were three instances of possible intrauterine WNV infection: one infant fatality with lissencephaly following WNV infection that may have occurred in-utero; one instance of neonatal rash and discovery of recent WNV infection at one month of age; and one instance of neonatal WNV neuroinvasive disease at 9 days of age. In addition, two of 68 live-born infants had congenital microcephaly and no laboratory evidence of intrauterine WNV infection. Clinical follow-up on the development of these 68 infants is ongoing.

For the patient, participation involves providing informed consent for the collection of the following: diagnostic specimens at time of delivery; prenatal maternal health information; infant health information from birth; and routine health exams at two, six, and 12 months.

For the healthcare provider, participation involves the following: obtaining patient informed consent (forms included), completing and returning signed consent forms to CDC, completing brief clinical surveillance forms for consenting mothers and/or their infants, and collection of diagnostic specimens. Our staff will contact providers and appropriate laboratory staff approximately one month prior to the patient's estimated delivery date to further coordinate the collection of information and specimens at the time of patient's delivery. CDC will cover the costs of shipping and WNV testing of diagnostic specimens.

Diagnostic specimens collected at time of delivery, and planned tests:
Maternal serum (1 ml or more) for serology, PCR and, if +, virus isolation
Cord serum (1 ml or more) for serology, PCR and, if +, virus isolation
Cord tissue (fresh, cross section) for PCR, and, if +, virus isolation
Placental tissue (fresh, full thickness) for PCR, and, if +, virus isolation
Colostrum or breast milk (1 ml or more) for serology, PCR and, if +, virus isolation

Following delivery, our staff will contact the infant's pediatrician or primary health care provider to obtain follow-up clinical information from two-, six- and 12-month routine health exams.

We will strictly honor patient confidentiality throughout this process. We will notify physicians of test findings as soon as they are available. We will also relay results to cooperating state health department contacts.

We thank you in advance for your willingness to participate, and please feel free to call me at 970-266-3525 or Ms. Stephanie Kuhn at 970-266-3572 if you have any questions or concerns.

Sincerely,

Dan O'Leary



Surveillance registry for birth outcomes of pregnancy-associated West Nile virus infection in the United States

Consent Form: Page 1 of 3

Please return completed forms by mail or fax to:
CDC/Arboviral Diseases Branch
Attn: Stephanie Kuhn
Foothills Campus
Rampart Road
Fort Collins, CO 80521
FAX: (970) 266-3568

For adults ≥ 18 years of age able to give consent

Name _____ Date of birth _____

Please feel free to ask any questions you may have about this registry and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. You will be given a copy of this consent form.

Introduction & Purpose

West Nile virus is a virus that first appeared in the United States in 1999. The virus is transmitted to people by infected mosquitoes. In some cases, West Nile virus can cause serious illness affecting the brain or spinal cord.

The United States Centers for Disease Control and Prevention has developed a registry to collect information about West Nile virus infections during pregnancy. This registry will allow us to learn how often West Nile virus is passed in the womb from pregnant mother to child. This will also help us see if West Nile virus affects the health of pregnant women and the health and development of infants. This information will help to guide in future prevention efforts.

Procedures

We are asking you to be in this registry because you had a West Nile virus infection during your pregnancy. You are free to join this registry or not. If you agree to be part of this registry, we will ask the doctors caring for you and your child some questions about your health and your child's health at the time of delivery. In addition, we will ask your permission to collect samples of blood or tissue from you and your child at the time of delivery. You can refuse to give any or all of these samples if you do not want to participate.

If you participate, we will ask your doctor to collect the following samples at the time of delivery:

- 1) A 5 ml (one teaspoon) sample of your blood which may be taken during blood draw for your care
- 2) A 5 ml sample of your child's blood taken from the umbilical cord after its removal
- 3) A section of the umbilical cord after its removal
- 4) A section of the placenta after its delivery
- 5) A 2-5 ml sample of your first milk or, if that is not available, a sample of breast milk taken from the week following your delivery
- 6) A 5 ml sample of your child's blood **only** if blood from the umbilical cord was not available at delivery or if West Nile virus infection is suspected from laboratory testing of your child's other samples. We may request this specimen up to 8 months following your child's birth.
- 7) **Only** if your doctor needs to take spinal fluid from your back or your child's back for your clinical care, we would like to test any leftover fluid. If available, we will test leftover spinal fluid to look for West Nile virus infection.

We will test these samples to determine if your child was infected in the womb with West Nile virus. We will inform your physician when the test results are available

In addition to testing for West Nile virus infection, we would also like to ask your pediatrician more questions about your child's health at two months, six months, and one year following your child's birth.

The medical care you are given is routine medical care and is not experimental or being done as part of the registry.



Risks or Discomforts

Risks to you from being in this registry are small. You will feel a pin prick when the blood is taken. The hurt will be over quickly. This may leave a small bruise. Also the amount of blood we take is small (approximately 2 teaspoons) and will not harm you at all. All the needles and procedures we will use are germ-free and new. Umbilical cord blood, umbilical cord tissue, and placental tissue are normal products of birth. Collecting these will not cause your child any pain or health risk.

In special instances, we may ask to collect a small sample of blood from your child. For example, if you were ill with West Nile virus infection within two weeks before your child's delivery, samples collected at delivery may not tell whether your child was infected in the womb and we may ask to collect a small sample of blood from the child at one month of age. For another example, if the specimens collected at delivery suggest that your child may have been infected with West Nile virus in the womb, we may ask to collect a small sample of blood from the child after six months of age. S(he) will feel a brief pin prick when the blood is taken. The discomfort will be over quickly. This may leave a small bruise. The amount of blood is small (about one fifth of one teaspoon) and will not harm your child at all.

Benefits

Because there is no treatment for West Nile virus, the special testing of samples for West Nile virus infection will not help the doctor take care of your child. The results may help show whether there are health risks from West Nile virus infection during pregnancy.

Confidentiality

We will keep what we talk about today and all test results as private as we can by law. To protect your and your child's privacy, we will keep the records and the blood tube under a code number rather than by your name. Only registry staff will be allowed to look at your information and test results. The code that links a registry number to your name will be kept by registry staff in locked files. Your name or other facts that might point to you will not appear when we talk about this registry or publish its results.

Cost/Payment

West Nile virus testing of the samples from you and your child will be part of the study and will not cost you anything.

Alternatives

You will receive the same care whether or not you join the registry, or if you join the registry and then drop out.

Right to Refuse or Withdraw

You are free to join the registry or not. If you decide to join, you are also free to change your mind at any time for any reason. You will receive the same care whether or not you join, or if you join and then drop out. If you choose to leave the registry, you can ask us to make sure that all of your forms, test results and stored samples are destroyed, and we will follow your instructions.



Surveillance registry for birth outcomes of pregnancy-associated West Nile virus infection in the United States

Consent Form: Page 3 of 3

Persons to Contact

If you have any questions or concerns regarding this surveillance registry, please contact us at any time. Also, if you want to stop participating in the registry at any time, please let us know and we will promptly honor your request.

Daniel R. O’Leary, DVM, DACVPM
Arbovirus Disease Branch
Division of Vector-Borne Infectious Diseases
NCID/CDC
Rampart Rd/Campus West
Fort Collins, CO 80521
DOleary@cdc.gov
Tel: (970) 266-3525

Consent for registry:

If you have read this consent form, had an opportunity to discuss with your health care provider, and agree to participate in the registry, please sign at the space indicated below.

Signature of patient

Date

Signature of the physician/representative

Date

Thank you for agreeing to be in our registry. We would also like to store your blood, spinal fluid, and other samples to use in the future to look for other causes of encephalitis. We will not use your samples to perform genetic testing or HIV testing. If the testing gives us information that could be important for your health, we will notify you and your doctor about that information. If you decide to leave the registry, we will make sure that all of your forms, test results and stored samples are destroyed. You may still agree to take part in the registry even if you decide you do not want your samples to be stored.

Consent for sample storage and future testing:

If you agree to allow us to store your samples for future testing, please sign below.

Signature of the patient

Date

Signature of the physician/representative

Date

Pregnancy-associated West Nile virus (WNV) surveillance form

These data are strictly confidential and will be stored in a secure database at the Centers for Disease Control and Prevention, Division of Vector-Borne Infectious Diseases, Fort Collins, CO, 80521



Please return completed form by fax to (970) 266-3568
Contacts: Ms. Stephanie Kuhn: (970) 266-3572, skuhn@cdc.gov
Dr. Dan O'Leary (970) 266-3525, doleary@cdc.gov

Mother's health history

Mother's name:

(Last, First) _____ **DOB:** ____/____/____

State of residence: _____ **County of residence:** _____

Race: American Indian or Alaska Native Asian Black or African-American Native Hawaiian or other Pacific Islander White Other: _____ Unknown

Ethnicity: Hispanic or Latino Not Hispanic or Latino Unknown

Mother's WNV illness

Date of WNV illness onset: ____/____/____

Clinical category of mother's WNV illness: (check all that apply)

West Nile Fever West Nile Meningitis West Nile Encephalitis Asymptomatic
 Acute Flaccid Paralysis (AFP) Other Clinical Presentation _____

Mother's pregnancy

Last Menstrual Period: ____/____/____ **Estimated delivery date:** ____/____/____

Gestation history: Gravida ____ Para ____ SAB ____ TAB ____

Underlying maternal illness: Yes (please describe) No Unknown

Complications of pregnancy: Yes (please describe) No Unknown

Fetal abnormalities detected in utero: Yes (please describe) No Unknown

Did this pregnancy end in miscarriage? Yes (date: ____/____/____) No

Type of delivery: Vaginal Forceps/suction Cesarean section

Maternal temperature at delivery: _____ Unknown

Blood transfusion given to mother: Yes No Unknown

Does mother plan to breastfeed? Yes No Unknown

Provider information

Provider name: Dr. PA RN Mr. Ms. **Phone:** _____
(Last, First) _____ **Fax:** _____

Name of person completing form: (if different from provider) **Hospital/facility:** _____
(Last, First) _____ **Phone:** _____

FOR INTERNAL CDC USE ONLY

Mother ID: _____ **State ID:** _____

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Infant assessment at delivery

Infant's name: (Last, First) _____ **DOB:** ____/____/____

State of residence: _____ **County of residence:** _____

Gender: Male Female **Gestational age at delivery:** _____ weeks by infant exam

Apgar score: 1 min ____ / 5 min ____ **Infant temperature at delivery:** _____ Unknown

Birth weight: _____ kg lbs/oz **Length:** _____ cm in **Head circumference:** _____ cm in

Seizures: Yes No Unknown **Cataracts:** Yes No Unknown **Skin rash:** Yes No Unknown

Chorioretinitis: Yes No Not assessed Unknown **Normal tone:** Yes No Unknown

Congenital anomalies: Yes (please describe) No Unknown

Focal neurologic deficits: Yes (please describe) No Unknown

Hearing evaluation performed: Normal Abnormal (please describe) Not Done

Imaging study performed: No Yes (date: ____/____/____ and imaging study type: _____)

Imaging study result: N/A Normal Abnormal (if abnormal, please describe)

TORCH testing: if positive, please specify test (i.e. PCR, IgG, IgM)

	Toxoplasmosis	Rubella virus	Cytomegalovirus	Herpes simplex virus	Syphilis	Varicella	Other
positive							
negative							
results pending							
not tested							

Provider information

Provider name: Dr. PA RN Mr. Ms. **Phone:** _____

(Last, First) _____ **Fax:** _____

Name of person completing form: (if different from provider) **Hospital/facility:** _____

(Last, First) _____ **Phone:** _____

FOR INTERNAL CDC USE ONLY

Mother ID: _____ **State ID:** _____

Pregnancy-associated West Nile virus (WNV) surveillance form

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Dr. Dan O'Leary (970) 266-3525, doleary@cdc.gov

Infant follow up: 2 months 6 months 12 months

Infant's name: *(Last, First)* _____ **Date of exam:** ____/____/____

Weight: _____ kg lbs/oz **Length:** _____ cm in **Head circumference:** _____ cm in

Infant physical exam: Normal Abnormal *(please describe)*

Infant development: Normal Abnormal *(please describe)*

Special studies since last follow-up

(Please summarize any results)

CT/other imaging scan: Yes No

Hearing evaluation performed: Yes No

Dysmorphology exam: Yes No

Ophthalmologic exam: Yes No

Other *(please describe)*: Yes No

Provider information

Provider name: Dr. PA RN Mr. Ms. **Phone:** _____
(Last, First) _____ **Fax:** _____

Name of person completing form: *(if different from provider)* **Phone:** _____
(Last, First) _____ **Fax:** _____

FOR INTERNAL CDC USE ONLY

Mother ID: _____ **State ID:** _____