Draft—Ethics cases on Zika

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# Case 1—Testing for Zika

Infection with Zika virus in pregnant women is a major global concern because of its linkage to congenital abnormalities including microcephaly, spontaneous abortion, and intrauterine growth restriction.(1) In addition, Zika infection has been associated with severe neurologic disease and Guillain–Barré syndrome, particularly among older adults.

An infected bite from a female *Aedes aegypti* mosquito is believed to be the primary mode of transmission of Zika, but infection through sexual transmission has also been reported. Viral persistence in the testes and semen has been described, and the window of sexual transmission remains uncertain, which has led to much uncertainty, particularly for couples trying to get pregnant.

Data supporting vertical infection and a causal role for Zika in the development of congenital malformations include the detection of Zika RNA or antigen in the amniotic fluid, the placenta, or the brain tissues of fetuses or infants in whom microcephaly is diagnosed after death in utero or soon after birth. Moreover, a prospective study involving Zika-infected pregnant women in Brazil showed that 29% of fetuses had gestational abnormalities including microcephaly and intrauterine growth restriction, which in a subgroup of cases resulted in fetal death.

Testing for Zika is surprisingly complex, and may require three tests to confirm a positive result.(2) One test is called a polymerase chain reaction (PCR), designed to detect the active virus in blood and urine. But the PCR test is reliable only if used within 1-2 weeks of exposure. Since most infected people lack symptoms for Zika, many cannot pinpoint the date of exposure.

When a PCR test is negative, the next step is to test the blood sample for Zika [antibodies](http://health.nytimes.com/health/guides/test/antibody-titer/overview.html?inline=nyt-classifier). A negative antibody test means a person was not exposed to Zika. But a positive result may require a third test, since there is cross-reaction with other viruses, such as dengue and chikungunya, both of which cause flu-like symptoms and are present in Central and South American countries.

The third type, the plaque reduction neutralization test (PRNT), determines conclusively whether a person was exposed to Zika. In the U.S., this test is done by the [Centers for Disease Control and Prevention](http://www.cdc.gov/zika/symptoms/diagnosis.html) (CDC) and a limited number of local health department laboratories. However, it requires Biosafety level 3 laboratories.

For men, the story is even more complicated. Infected men can carry Zika in their semen for a certain period, but there is no approved test for screening semen.

As worries about the spread of the virus in the US continue to mount, public health department labs in Florida and New York City are running at or close to capacity, while private commercial labs have won emergency approval to run Zika tests, and have ramped up their testing capacity. Public health officials in Florida face a backlog of tests for pregnant women, some of whom may be waiting to make decisions about whether to have abortions if they test positive.

The CDC has issued restrictive guidelines about who should be tested, giving priority to pregnant women with possible exposure to Zika and to people with Zika-like symptoms. This testing policy largely ignores a sizable subgroup of women and men who are also at risk — those who are trying to conceive but fear that they have been exposed to Zika. The CDC recommends that women contemplating [pregnancy](http://topics.nytimes.com/top/news/health/diseasesconditionsandhealthtopics/pregnancy/index.html?inline=nyt-classifier) avoid travel to areas where Zika transmission is occurring and, if they have traveled, recommends that they wait at least eight weeks before trying to conceive. But it currently does not recommend testing.

Both the CDC and the [World Health Organization](http://www.who.int/mediacentre/factsheets/zika/en/) now recommend six months of protected sex for both men and women after Zika exposure.(3) But neither group recommends testing.

These restrictions are aimed at preventing an onslaught of requests for Zika tests that could further clog the system and prevent public health officials from identifying new cases expediently. Consider the analogy of the excess number of specimens submitted to government labs following the post 9/11 anthrax scare in the U.S. After 6+ deaths from respiratory anthrax, some connected to inhalation of white powder that may have been weaponized anthrax, specimens of white powder including talcum, powdered sugar and others were submitted to labs across the U.S. for testing in such numbers that labs were overwhelmed.

Testing without adequate counseling could compound the problem. Tests also shape medical practice and influence insurance coverage, making doctors reluctant to order tests and insurers unwilling to cover the costs — between $229 and $800 on the private market — if patients don’t fit the CDC’s testing criteria.

Many public health experts say that the restrictions are necessary to ensure that people most at risk have access to testing. “We aren’t interested in stimulating the testing of simply anxious people,” said Dr. William Schaffner, an [infectious diseases](http://health.nytimes.com/health/guides/specialtopic/travelers-guide-to-avoiding-infectious-diseases/overview.html?inline=nyt-classifier) specialist and the head of [preventive medicine](http://health.nytimes.com/health/guides/specialtopic/preventive-health-care/overview.html?inline=nyt-classifier) at Vanderbilt University Medical Center. “We want health care providers to provide the appropriate counseling and to be selective in the use of this test, as they are in the use of any other test.”(2)

Some medical groups are pushing back against the CDC guidelines. The [American Society of Reproductive Medicine](https://www.asrm.org/?vs=1), a membership organization representing fertility experts, recommended that men and women who may have been exposed to Zika consider being tested and embark on fertility treatments only if tests are negative.

## Scenario

Given the reluctance of many government labs to provide testing to whoever comes forward, the following questions have been put forward to the local state lab:

1. Should testing be offered to all who want it regardless of possible risks as defined by travel or symptoms after possible exposure?
2. Should testing be offered to men, with or without a history of symptoms, who have visited areas where Zika has been reported? If so, what level of Zika incidence defines an area as high risk?
3. Should testing be given to couples who are planning on pregnancy but want to be sure that both partners are Zika free, especially as one may have been exposed to the virus through recent travel or residence?
4. Should testing be limited to pregnant women in their first-trimester only because they are thought to be at greater risk of delivering a child with malformations due to congenital Zika syndrome?
5. If the state refuses to provide testing for a man or a woman but their physician believes they have a legitimate claim to be tested and they cannot afford the private test, should the state make an exception and perform the test?
6. Who is liable if a child is born with congenital Zika syndrome and despite parental request, testing has not taken place because the physician was following the CDC guidelines?

(1) Mysoekar, I. U. et al ”Modeling Zika Virus Infection in Pregnancy, N Engl J Med 2016; 375:481-484, [August 4, 2016](http://www.nejm.org/toc/nejm/375/5/)

(2) Roni Caryn Rabin, ”Want a Zika test? It’s Not Easy”, The New York Times, September 19, 2016

(3) Stein, R., “CDC Tells Men At Risk Of Zika To Put Off Procreation For 6 Month”, NPR. September 30, 2016

# Case 2—Advising a Woman with Suspected Zika Infection

The Zika virus epidemic is spreading: 67 countries are now reporting transmission, and over 2,000 cases of congenital Zika syndrome have been confirmed.

The heaviest burden has been borne by those living where poverty, poor infrastructure, and lack of access to health services are common and the penetration of *Aedes aegypti* is high. Because most cases are asymptomatic, the most dramatic signs of the disease appear through the congenital Zika syndrome. In spite of the need for disaggregated epidemiological data to understand transmission patterns and evaluate interventions in vulnerable populations, there is no reliable count of Zika cases by sex and ethnicity.(1)

WHO’s interim guidance on pregnancy management in the context of Zika virus infection includes recommendations for preventing and managing infection in pregnant women. Vector control is emphasized, as well as personal protection such as clothing, bed nets, repellents, and safe sex.(2) These recommendations, duly relayed by health authorities, don't always resonate in the poorest neighborhoods of Brazil, El Salvador and other affected countries, where the availability, practicality, and affordability of protective items are doubtful and where safe sex is not always negotiable. When prevention fails, pregnant women and other women of reproductive age are faced with difficult decisions against a background of uncertainties.

Basic reproductive services may be lacking or inaccessible. In many cases, restrictive abortion laws curtail their ability to thwart the consequences of the virus for their health and that of their children

El Salvador, a Central American country with a population of 7 million, most of whom are Roman Catholic or Evangelical Christians, has been hit by Zika. There have been an estimated 5400 cases of Zika infection, 100 of which were in pregnant women. El Salvador has urged all women to delay pregnancy until 2018. In Central America it is estimated that 74% have access to contraceptives. With physicians across Central and Latin America urging women to postpone pregnancy because of the Zika virus, Pope Francis said that using contraceptives could be a "lesser evil" when a baby would have a high risk of birth defects, but he added, "Abortion is not a lesser evil -- it's a crime. It is the deliberate taking of an innocent human life…It's an absolute evil...Don't confuse avoiding pregnancy with abortion."(3)

The government of El Salvador has some of the strictest anti-abortion laws. Abortion is banned without exception, including after rape, incest, severely deformed fetus diagnosis, and when a woman’s life is in danger. Under Salvadoran law, doctors must report women whom they suspect of having induced an abortion. It is strictly illegal for doctors to provide abortive services and to advise on how to procure them.

The Citizen Group for the Decriminalization of Therapeutic, Ethical, and Eugenic Abortion (CFDA), a local rights group, says the abortion ban causes maternal deaths by forcing women to undergo dangerous back street abortions. An estimated 35,000 clandestine abortions take place in El Salvador every year. The rights group says that scores of women have been wrongly convicted of murder and imprisoned when they in fact suffered miscarriages, stillbirths or pregnancy complications. Of the 147 women prosecuted for abortion-related crimes between 2000 and 2014, 25 remain in jail, with some serving sentences as long as 40 years, the CFDA says. The legal ban particularly affects poor women, who cannot travel abroad to private clinics.(4)

Resistance to changes to the ban comes not only from the Catholic church and evangelical groups but from conservative lawmakers and the left-wing ruling FMLN party that fears alienating voters.

## Scenario:

A woman, from one of the barrios of the capital, San Salvador, presents at a local clinic for her first prenatal visit when she is 20 weeks pregnant. She gives a history that is consistent with an acute Zika infection when she was 12 weeks pregnant. The doctor tests her for Zika and she has antibodies consistent with a past infection. A brain scan shows evidence of early calcifications. The doctor informs the patient of her findings and the consequences of the Zika infection. The woman is devastated. She has three other children less than 7 years of age and her husband is a day laborer. The patient pleads with the doctor to give her advice on what she can do to prevent the birth. The doctor, who supports a woman’s right to choose and is a member of CFDA, knows that safe abortions can be had within the city at a price that may be affordable to the woman.

* What should the doctor recommend?
* Should she give the woman a set of choices that include an illegal act, punishable under the law?
* What if the patient cannot afford an in-country abortion?
* Does the doctor have a duty to her patient that transcends the law of the land?
* Does it matter what the doctor’s personal beliefs on abortion are?
* Does it matter that El Salvador is a democracy and a majority supports highly restrictive abortion laws?
* Does it matter that according to a recent [Pan American Health Organization guidance document](http://iris.paho.org/xmlui/bitstream/handle/123456789/28425/PAHOKBR16002_eng.pdf?sequence=1&isAllowed=y), all governments are bound by a duty to provide information, respect the right to choose, and provide access to comprehensive reproductive health care and social support to women affected by Zika and their children? (2)

(1) The Lancet, The rights approach to Zika, 7:4, e427, July 2016

(2) PAHO, Zika Ethics Consultation, April 6-7, 2016

(3) Catholic New Service, 2-19-2016

(4) Fox News, “Zika looms but El Salvador stands firm on abortion ban, May 23, 2016