Emergency Legal Preparedness and Zika Virus: A Primer

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Brief Overview - 2015-17 Zika Virus Outbreak

International Legal Response Efforts

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Foreign Governments

U.S. Legal Preparedness/Response

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Zika Virus - Quick Facts

Transmission:

- Primarily through bites from the *Aedes* species of mosquito
- From pregnant mother to baby
- Through sexual contact, infected blood transfusions, and potentially bodily fluids (e.g., urine, saliva, breastmilk, stool in particularly ill patients)
- Virus remains in blood for 1-2 weeks, urine up to 14 days, semen up to 188 days after symptoms

Symptoms:

- Usually within 2-14 days, fever, rash, joint/muscle pain, conjunctivitis, and headache among 20% of infected
- Only 1 in 5 infected persons have any symptoms

Treatment:

- No vaccine, cures, or accepted treatments (other than addressing symptoms via rest and ample fluids)
Paths to Zika Transmission

Image concept attributed to Dr. William Shaffner, Chief of Preventative Medicine, Vanderbilt University School of Medicine
How Zika Spreads

PROTECT YOUR FAMILY AND COMMUNITY:
HOW ZIKA SPREADS

Most people get Zika from a mosquito bite

A mosquito bites a person infected with Zika virus

A mosquito will often live in a single house during its lifetime

The infected mosquito bites a family member or neighbor and infects them

More mosquitoes get infected and spread the virus

More members in the community become infected

The mosquito becomes infected

Other, less common ways, people get Zika:

During pregnancy
A pregnant woman can pass Zika virus to her fetus during pregnancy. Zika causes microcephaly, a severe birth defect that is a sign of incomplete brain development

Through sex
Zika virus can be passed through sex from a person who has Zika to his or her sex partners

Through blood transfusion
There is a strong possibility that Zika virus can be spread through blood transfusions
Zika Virus – Epi

Confirmed Links:
• Pattern of birth defects collectively know as **Congenital Zika Syndrome** (found in **10% of U.S. births** among infected mothers) which can take up to 5 months to detect, absent abnormality
  • Microcephaly
  • Problems with brain development
  • Vision problems
  • Hearing loss
  • Joints with limited range of motion
  • Muscle tone restricting body movement
  • Cerebral palsy
  • Epilepsy

Suspected Links:
• **Guillain-Barré Syndrome** (strong association found by WHO & CDC)
• Pregnancy losses and **fetal hydrops**
• Potential **brain damage in adults**
International Legal Response Efforts
Zika Virus Global Distribution

Purple - prior cases
Orange – very recent cases

For updated versions of this map, see: http://www.healthmap.org/zika/#timeline
February 1, 2016: Zika virus declared a Public Health Emergency of International Concern (PHEIC)

“After a review of the evidence, the committee advised that the clusters of microcephaly and other neurological complications constitute an extraordinary event and public health threat to other parts of the world.”

Dr. Margaret Chan, WHO Director-General

May 26, 2016: WHO announces expedited Health Emergencies program to streamline decision-making and provide aid more quickly

June 7, 2016: WHO advises men and women of reproductive ages living in areas of local Zika transmission to delay pregnancy

September 6, 2016: WHO clarifies its advice to offer counseling and contraceptives to couples in Zika-affected areas, but not to delay pregnancy

November 18, 2016: WHO declares the end of the Zika PHEIC
WHO Zika Virus Response Plan

Surveillance - strengthen surveillance focused on rates and clinical outcomes of GBS and microcephaly

Community Engagement & Risk Communication - relay information to key stakeholders

Vector Control & Personal Protection - determine most effective mosquito abatement strategies given local ecology, species behavior, & resources

Care - focus on health services preparedness and community engagement

Research - study the presence of Zika virus in bodily fluids related to transmission via unprotected sex and mother to child

Coordination - establish incident management teams to analyze diagnostics under development and vector control measures
<table>
<thead>
<tr>
<th>Country</th>
<th>Date Range</th>
<th>Type of Emergency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brazil</td>
<td>11/11/15 - 05/11/17</td>
<td>National Health Emergency</td>
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<tr>
<td>Mexico</td>
<td>1/22/16</td>
<td>Epi Health Emergency</td>
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<tr>
<td>Trinidad &amp; Tobago</td>
<td>1/29/16</td>
<td>Public Health Emergency</td>
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<tr>
<td>Tonga</td>
<td>2/1/16</td>
<td>Zika Outbreak</td>
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<tr>
<td>Honduras</td>
<td>2/2/16</td>
<td>National State of Emergency</td>
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<tr>
<td>Costa Rica</td>
<td>2/25/16</td>
<td>National State of Emergency</td>
</tr>
<tr>
<td>Peru</td>
<td>7/12/16 - 10/10/16</td>
<td>Health Emergency</td>
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U.S. Legal Response Efforts
Zika Virus Cases in the U.S.

For updated versions of the map, see: http://www.cdc.gov/zika/geo/united-states.html
U.S. Jurisdictions at Risk

U.S. Prevalence of *Aedes Aegypti* Mosquitoes
[based on monthly averages from 2006-2015]
1/27/16: President Obama calls for rapid development of tests, vaccines, and treatments to fight Zika virus

4/1/16: White House and CDC convene Zika Virus Summit for state and local actors, urging early action

7/1/16: President Obama calls for Congress to pass Zika funding to support research, prevention and development of a vaccine

7/15/16: HHS holds collaborative Summit to Accelerate Zika Diagnostics Development

8/3/16: NIH launches clinical trials of Zika vaccine
Following months of debate, Senate Democrats stymie Zika funding bill to prevent Republican blocking of Zika funds for Planned Parenthood.

House approves bill relaxing EPA standards for pesticide use by state/local governments.

House approves $1.1 billion Zika bill with $750 million taken from budget cuts to other health care programs.

Congress approves stopgap bill, providing $1.1 billion to fight Zika without Planned Parenthood restrictions.
Federal Agency Responses
2/26/16: There is a **significant potential for a public health emergency that affects, or has significant potential to affect, national security or the health and security** of U.S. citizens.

Food Drug & Cosmetic Act § 564

8/12/16: A **public health emergency of national significance** exists in Puerto Rico relating to pregnant women and children born to pregnant women with Zika.

Public Health Service Act § 319

2/10/17: **Liability immunity protections** are in effect for manufacturers, distributors, program planners, and qualified persons relating to the Zika virus vaccine.

Public Readiness & Emergency Preparedness (PREP) Act § 319F-4
Guidance issued suggesting individuals not donate blood if they have been to areas with active Zika virus, are exposed to the virus, or are infected.

Guidance issued on recommendations to reduce the potential transmission risk of Zika virus from human cells, tissues, and cellular/tissue-based products (HCT/Ps).

**FDA Takes Action against Zika Virus** - learn more about FDA's Zika response efforts in this blog post by FDA Commissioner Robert M. Califf, MD, and Acting Chief Scientist Luciana Borio, MD.

Requests blood centers in Miami-Dade County and Broward County cease collecting blood immediately until testing is possible.

Recommendations issued for testing all blood donations for Zika.

**Link here** for a complete list of multiple Emergency Use Authorizations (EUAs) issued by FDA for Zika-related tests & other products.
<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>1/15/16</td>
<td>Issues Travel Alert 2 re: many countries (except in higher elevations). <a href="#">Link here</a> for more info on safe travel locations</td>
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<tr>
<td>2/8/16</td>
<td>Elevates Emergency Operations Center to Level 1 to develop tests, study morbidity, do surveillance, &amp; support responses</td>
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<tr>
<td>6/14/16</td>
<td>Issues Draft Interim Response Plan outlining procedures upon first case of local Zika transmission on continental U.S. or Hawaii</td>
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<tr>
<td>7/1/16</td>
<td>Awards $25 million to states, cities and territories to support efforts to address Zika virus infection and related health outcomes</td>
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<tr>
<td>8/1/16</td>
<td>Issues first-ever domestic travel advisory for Zika “red zone” in Miami. This was removed on 6/2/2017</td>
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<tr>
<td>12/14/16</td>
<td>Designates Brownsville, Texas a Zika “yellow zone” following confirmed local transmission</td>
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<tr>
<td>3/13/17</td>
<td>Warns of risk of Zika infected semen in Miami Dade County sperm banks collected as far back as June 2016.</td>
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2/12/16-3/12/16: Hawai’i Governor David Ige declared a state of emergency re: Dengue fever and related mosquito-borne conditions, including Zika virus.
Emerging Legal Issues - Topics

- Travel Restrictions/Closures
- Mosquito Abatement
- Reproductive Health
- Surveillance & Reporting
- Employment/Privacy
- Liability & Insurance
- Testing, Screening, Treatment
- Public Health Preparedness
Topical Legal Issues

Localities in Houston announce plans to inspect private businesses & residences for breeding sources.

**FDA** issues Environmental Assessment for Oxitec genetically-modified mosquitos; no major environmental impacts.

**Opposition** to spraying of pesticide *Naled* leads to opposition in localities including P.R. and FL.

Thousands of male mosquitos with *Wolbachia bacteria* (causing female eggs to not hatch) were released in the Florida Keys.

Mosquito Abatement
Mosquito Abatement Techniques

Traditional Abatement Techniques

- Fumigation
- Source Reduction
- Repellent

Emerging Abatement Techniques

- Bacterial Infection
- Genetic Modification
- Nuclear Radiation
Topical Legal Issues

**NIH/NIAID panel** concludes Zika human challenge vaccine trial unjustifiable due to significant risks

**CMS** notes that state & private Medicaid funds may be used to cover mosquito repellent and other Zika-preparedness measures

**FDA** issues final guidance on EUAs that supports rapid response to Zika and other threats

**CDC** issues final rule to enhance surveillance and social distancing authorities in response to threats like Zika
Countries including Mexico, Ecuador, Argentina, Colombia, Costa Rica, & Jamaica advise women to delay pregnancy.

Affected countries face difficult legal and ethical issues re: lack of access to contraceptives & abortions.

Maternal/Child Health

Pres. Trump’s executive order cuts U.S. funding to international NGOs performing/advocating for abortions.

State abortion laws such as FL’s could prevent late-term abortions even where CZS is likely.
CDC establishes the Zika Pregnancy Registry and releases report on birth defects among infants with CZS.

Several states, such as NC, add Zika to the list of reportable diseases & conditions.

States including FL mandate that medical providers report Zika cases within 24-72 hours.

Zika virus disease and infection named to the list of Nationally Notifiable Conditions (2016-17).
Texas expands its 2017 testing recommendations for pregnant women in 6 counties and offers free tests for underinsured.

FDA advises testing of all donated blood for Zika; screening in PR suggests 1.1% of donated blood is infected.

CDC urges screening & testing of pregnant women within 2 weeks of their possible exposure to Zika.

ASPR supports clinical study to evaluate FDA cleared investigational test to screen blood donations.
HHS Secretary issues declaration to provide liability immunity protection for Zika vaccine-related activities.

San Juan, P.R. sues CDC over proposed aerial use of *Naled*. Suit dismissed when CDC agrees not to use *Naled* in P.R.

Residents in Miami-Dade County brought a federal lawsuit to prohibit spraying of Naled over residential areas, but the case was dismissed on civil procedure grounds.

Employers requiring travel to Zika-afflicted areas may be liable; EOC issues guidance on Zika-related employment issues.
Health Equity Issues

**Aedes aegypti** mosquitos breed in **stagnant water** often found in areas lacking modern sanitation, impacting poorer populations.

Inability to afford repellent, nets, screens, and air conditioning diminishes vulnerable groups’ prevention of **mosquito bites**.

Lack of **labs** and trained pathologists in developing countries limits testing and diagnosis.

**High population density** in overcrowded urban areas heightens risks of transmission.
For More Information

- Network for PHL
- WHO Zika Virus
- ASPR TRACIE

- CDC Zika Virus
- FDA Zika Virus
- APHA Zika Virus

Special thanks to Sarah Wetter and Rebecca Queensland at ASU’s Sandra Day O’Connor College of Law for their assistance with this Primer

Ask the Network concerning questions or comments relating to this information or ongoing Zika legal response efforts

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