

Emergency Legal Preparedness and Zika Virus: A Primer

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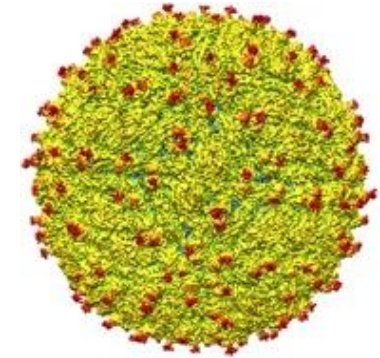
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Brief Overview - 2015-17 Zika Virus Outbreak

International Legal Response Efforts

World Health Organization

Foreign Governments



U.S. Legal Preparedness/Response

Additional Resources



Transmission:

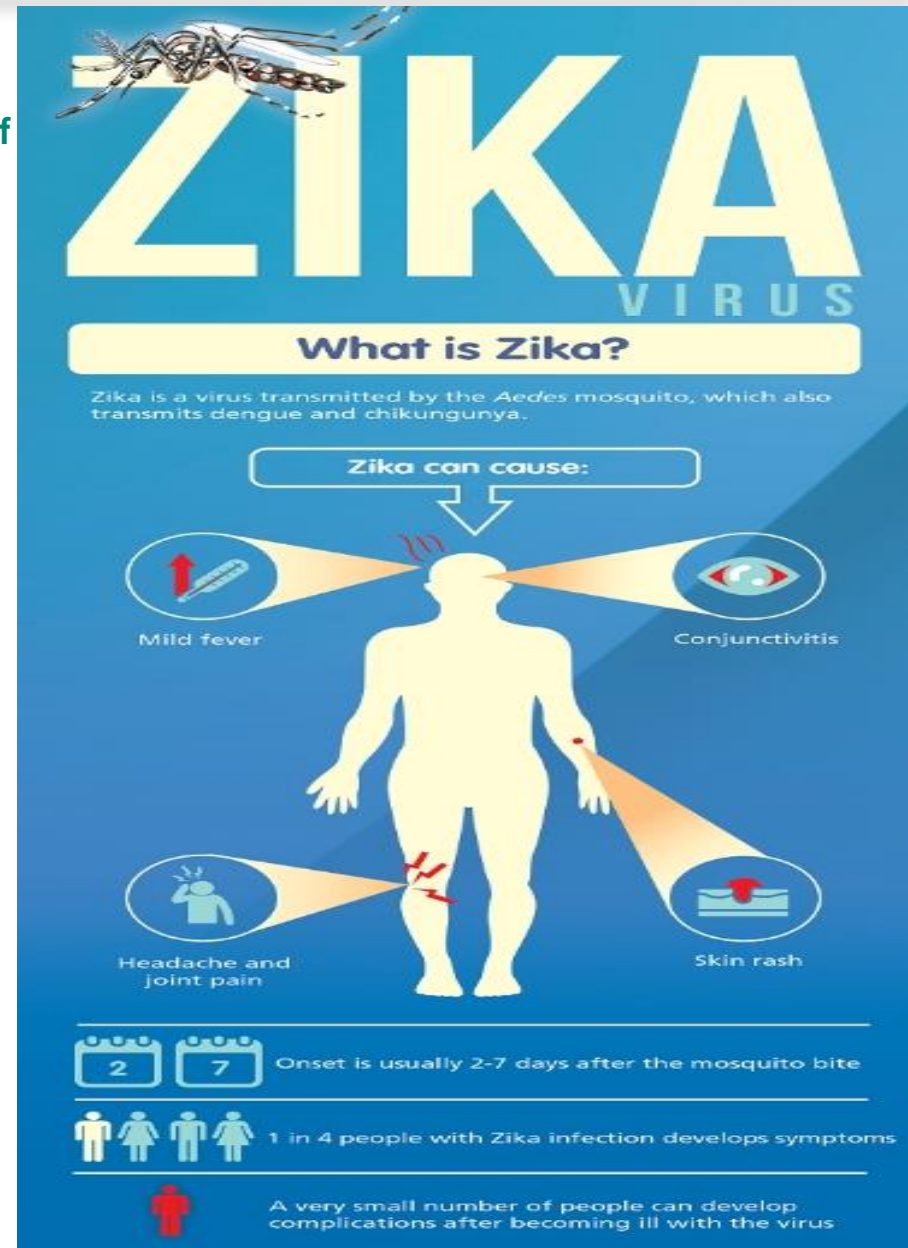
- Primarily through bites from the *Aedes* species of mosquito
- From pregnant mother to baby
- Through sexual contact, infected blood transfusions, and potentially bodily fluids (e.g., urine, saliva, breastmilk, stool in particularly ill patients)
- Virus remains in blood for 1-2 weeks, urine up to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

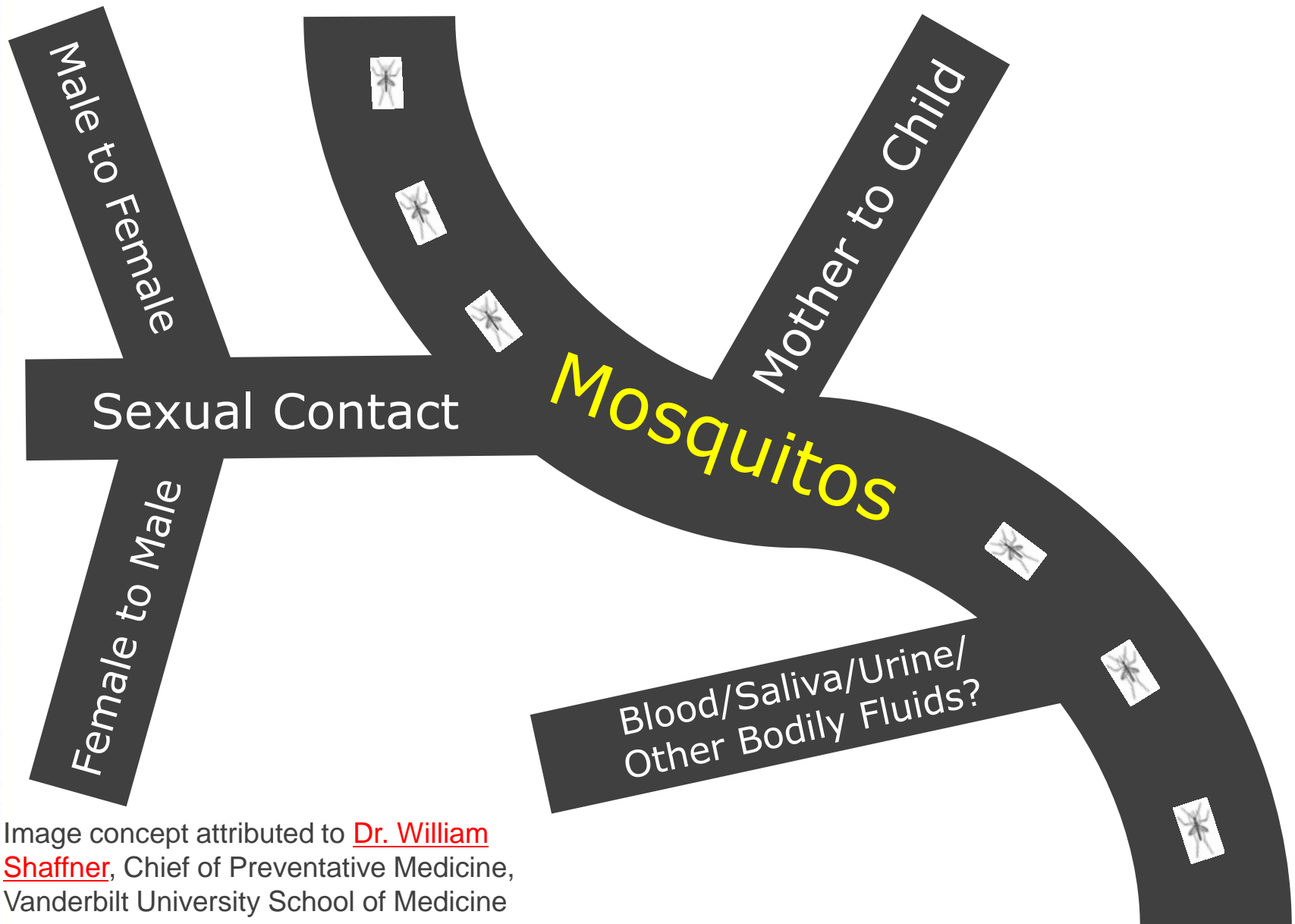
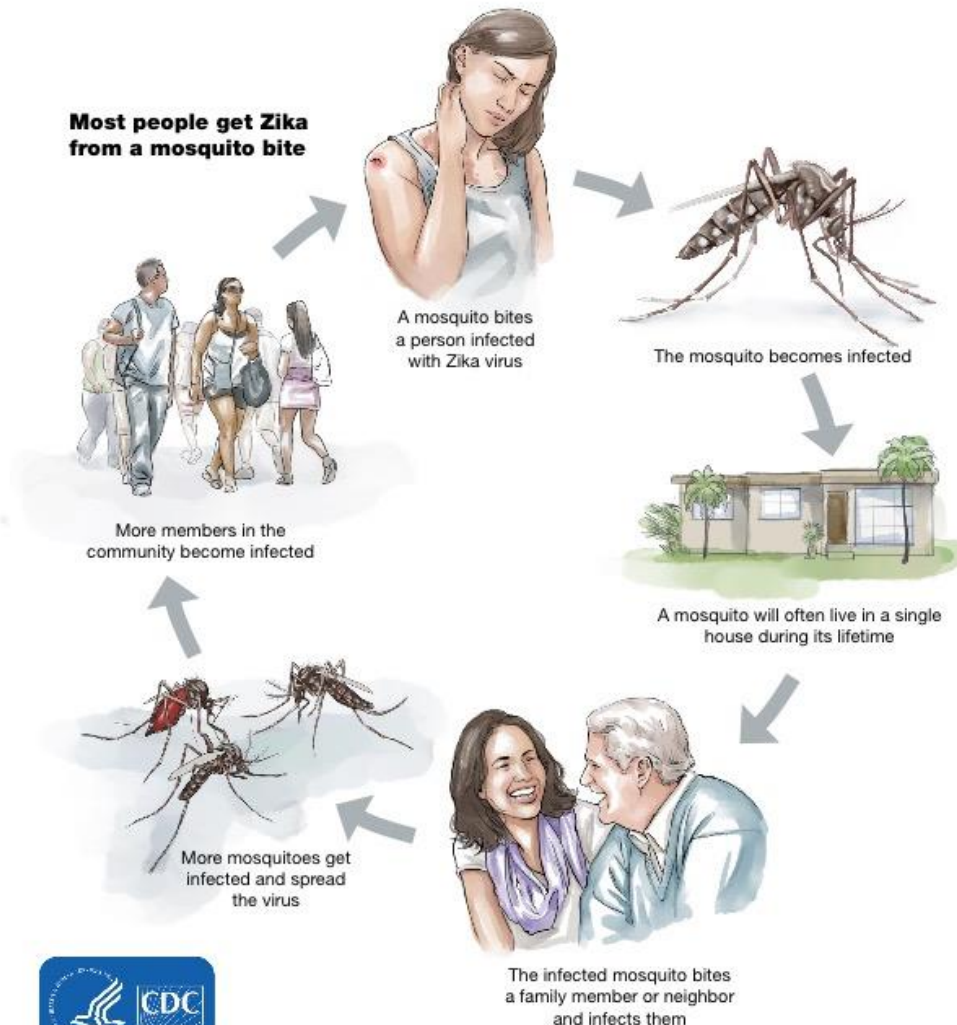


Image concept attributed to [Dr. William Shaffner](#), Chief of Preventative Medicine, Vanderbilt University School of Medicine

How Zika Spreads

PROTECT YOUR FAMILY AND COMMUNITY: HOW ZIKA SPREADS

Most people get Zika from a mosquito bite



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

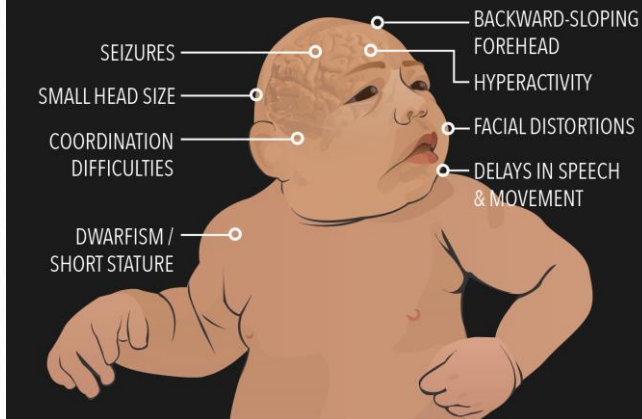
Through sex

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

SYMPTOMS OF MICROCEPHALY



Confirmed Links:

- Pattern of birth defects collectively known 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



For updated versions of this map, see:

<http://www.healthmap.org/zika/#timeline>

WHO Emergency Declaration

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



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



World Health
Organization



International Emergency Declarations



Brazil

11/11/15-05/11/17

National Health
Emergency



Honduras

2/2/16

National State of
Emergency



Mexico

1/22/16

Epi Health
Emergency



Marshall Islands

2/29/16-3/31/16

1/20/17-2/20/17

State of Health
Emergency



Trinidad & Tobago

1/29/16

Public Health
Emergency



Costa Rica

2/25/16

National State of
Emergency



Tonga

2/1/16

Zika Outbreak



Peru

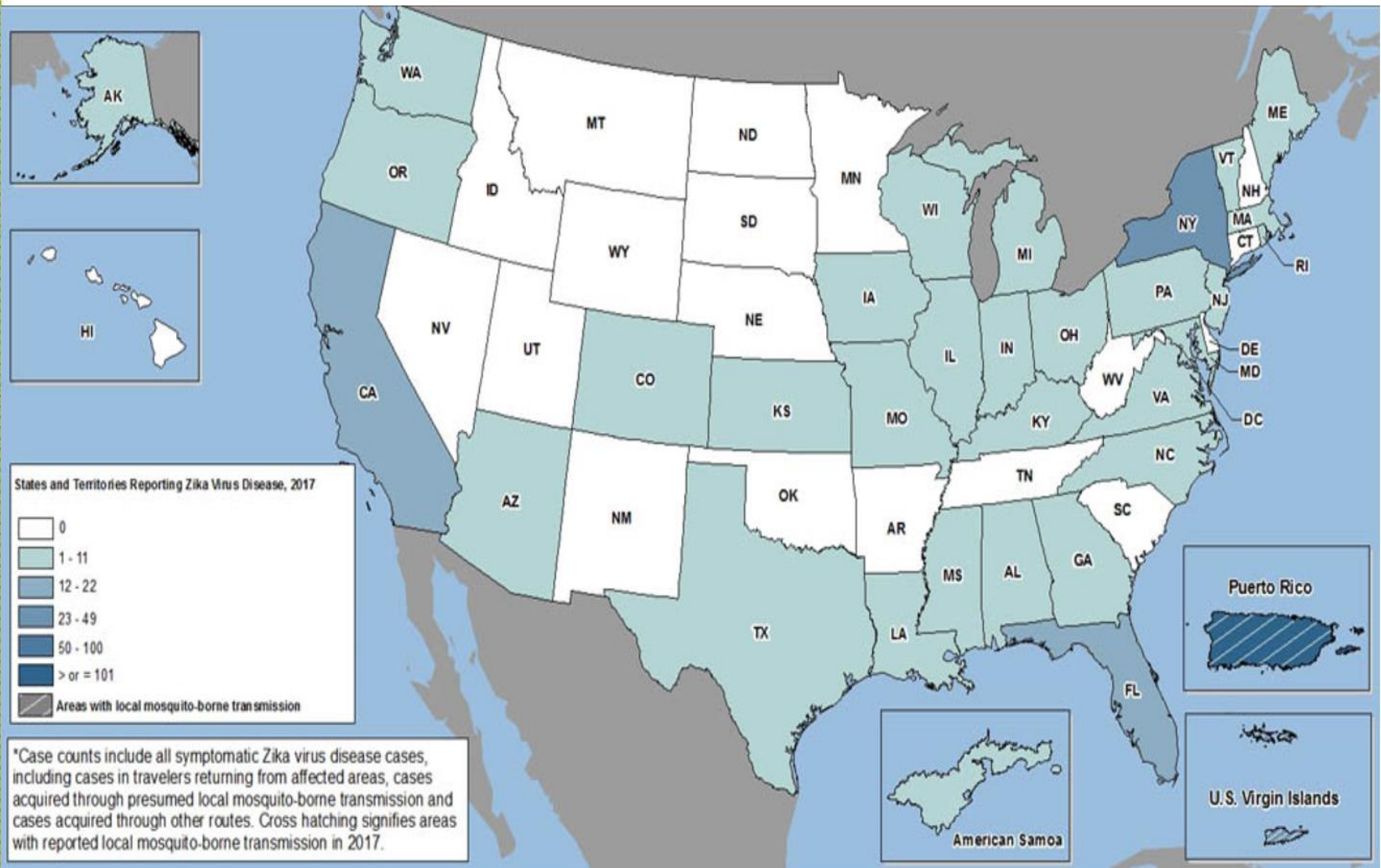
7/12/16-10/10/16

Health Emergency

U.S. Legal Response Efforts

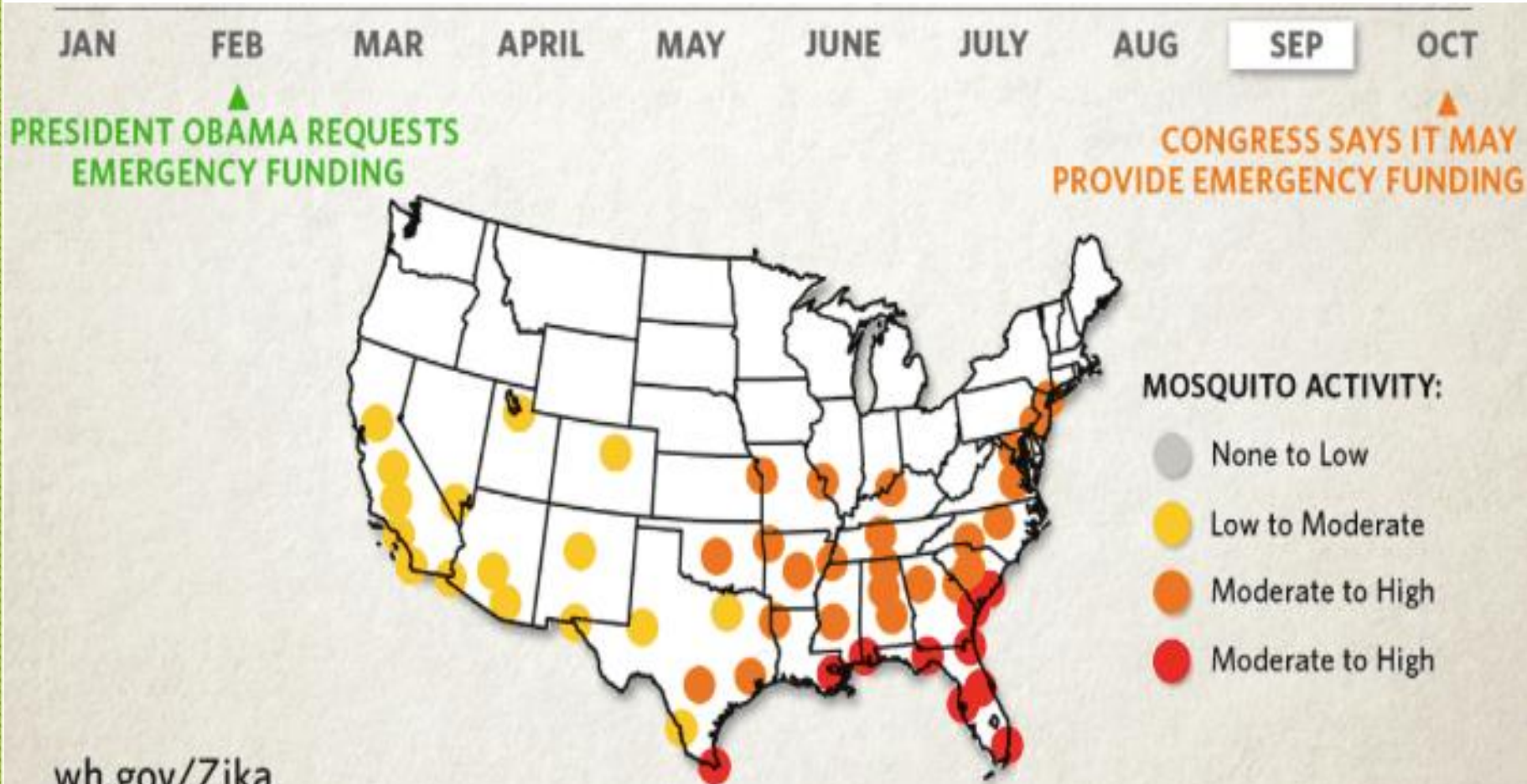


Zika Virus Cases in the U.S.



U.S. Jurisdictions at Risk

U.S. Prevalence of *Aedes Aegypti* Mosquitos [based on monthly averages from 2006-2015]



wh.gov/Zika

SOURCE: Monaghan et al. (2016) PLoS Current Outbreaks

U.S. Preparedness/Response



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



5/25/16

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



6/23/16

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

9/6/16

Following months
of debate, Senate
Democrats stymie
Zika funding bill to
prevent
Republican
blocking of Zika
funds for Planned
Parenthood



9/28/16

Congress
approves stopgap
bill, providing \$1.1
billion to fight Zika
without Planned
Parenthood
restrictions

Federal Agency Responses



HHS Public Health Emergency

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

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

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





U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

2/6/16

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

3/1/16

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

7/12/16

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

7/21/16

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

8/26/16

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

CDC Actions and Responses



Centers for Disease Control and Prevention

CDC 24/7: Saving Lives, Protecting People™

[Link here](#) for additional, varied guidance and resources from CDC

1/15/16

Issues Travel Alert 2 re: many countries (except in higher elevations). [Link here](#) for more info on safe travel locations

2/8/16

Elevates Emergency Operations Center to Level 1 to develop tests, study morbidity, do surveillance, & support responses

6/14/16

Issues Draft Interim Response Plan outlining procedures upon first case of local Zika transmission on continental U.S. or Hawaii

7/1/16

Awards \$25 million to states, cities and territories to support efforts to address Zika virus infection and related health outcomes

8/1/16

Issues first-ever domestic travel advisory for Zika “red zone” in Miami. This was removed on 6/2/2017

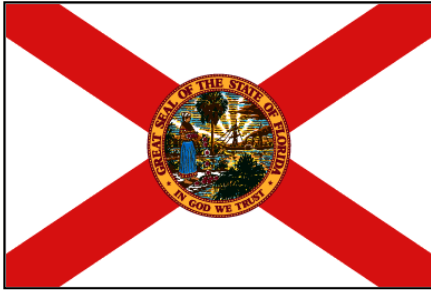
12/14/16

Designates Brownsville, Texas a Zika “yellow zone” following confirmed local transmission

3/13/17

Warns of risk of Zika infected semen in Miami Dade County sperm banks collected as far back as June 2016.

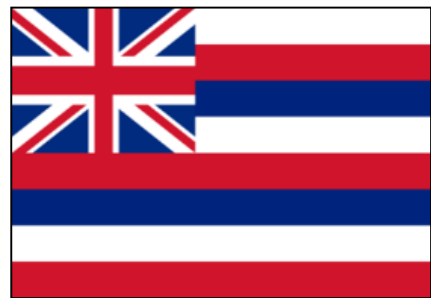
U.S. Based **Emergency** Declarations



2/3/16-4/9/17: Florida Gov. Rick Scott issued **Exec. Order 16-29** authorizing a public health emergency declaration in all counties with cases of Zika.

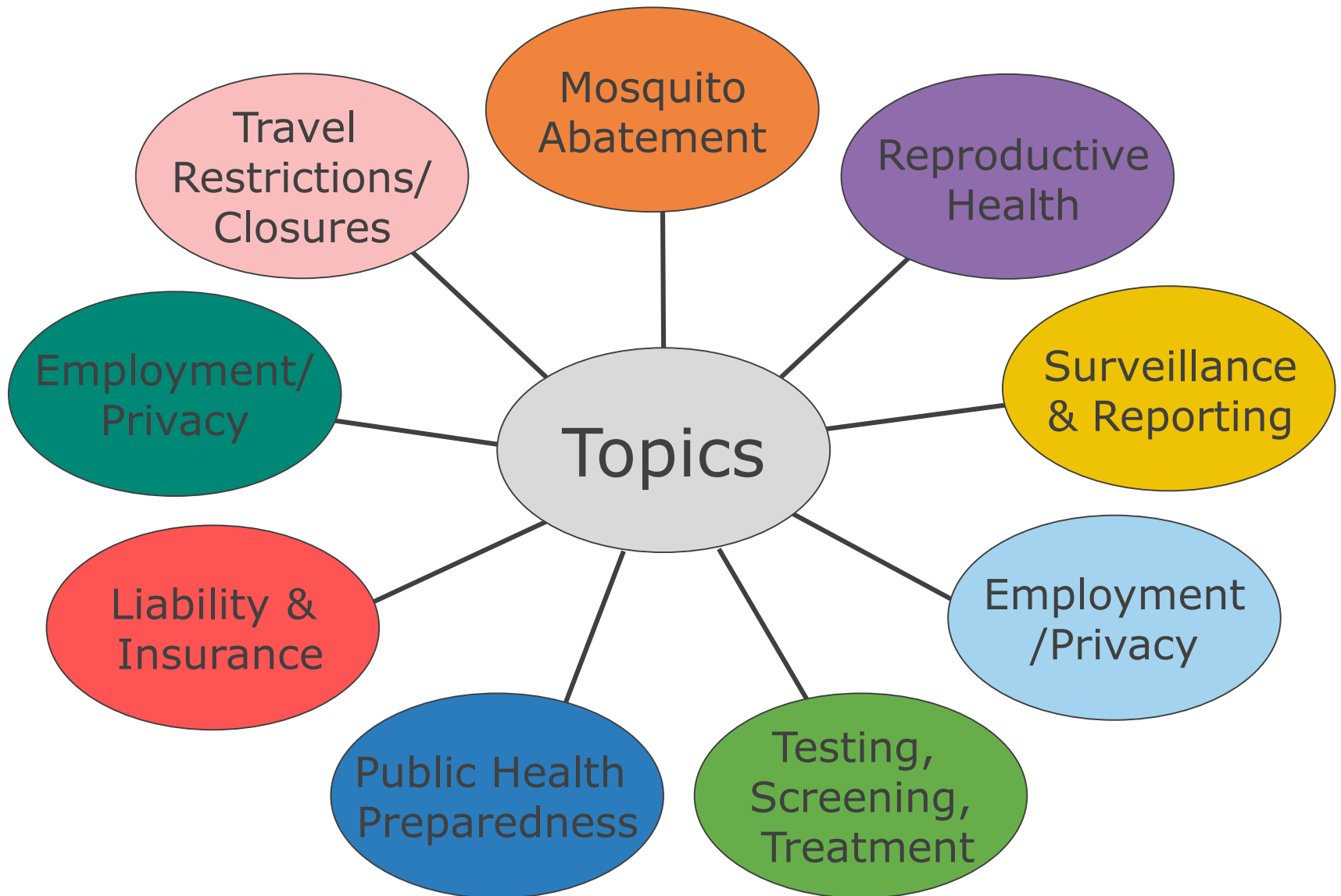


2/5/16-6/5/17: Puerto Rico Gov. Alejandro Garcia Padilla declared a territorial-wide public health emergency.



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



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

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

Mosquito Abatement

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

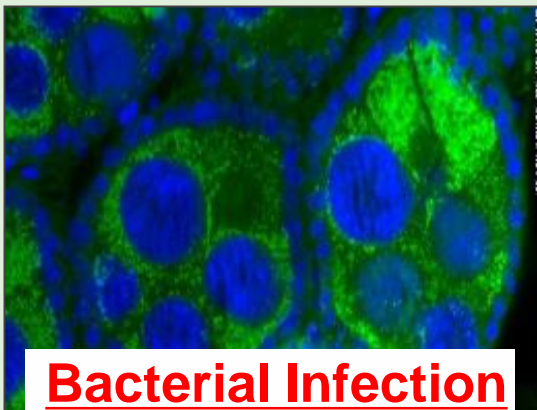
Thousands of male mosquitos with Wolbachia bacteria (causing female eggs to not hatch) were released in the Florida Keys

Mosquito Abatement Techniques

Traditional Abatement Techniques



Emerging Abatement Techniques



Public Health Preparedness

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

Surveillance & Reporting

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

Testing & Screening

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.

Liability & Insurance

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

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

Health Equity

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
- james.hodge.1@asu.edu