

Preventing Congenital Zika Syndrome: Lessons Learned from Rubella Elimination

Warkany Lecture
Teratology Society
June 25, 2017
José F. Cordero, MD, MPH

Dr. Josef Warkany



Fig. 1. Founders in the late 1950s. *From left to right:* James Wilson, F. Clarke Fraser, and Josef Warkany.

Source: Shepard, TS
TERATOLOGY 62:301–316
(2000)



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Key Points

- Zika is one of many emerging diseases the world would face in this century.
- Preparedness for emerging infections must be a priority
- There are lessons to be learned from Zika emergence and from Rubella elimination
- Control and elimination of Zika to prevent Congenital Zika Syndrome is a complex proposition that would require multiple strategies in order to succeed

Zika: The Road Ahead

- Zika Emergence is a call to:
 - Strengthen public health infrastructure at the local, state, national and global levels
 - Expand and strengthen collaboration between all sectors of community life including inserting public health in social media
 - Connect and speed up basic science, vaccine and product development and its translation to public health practice

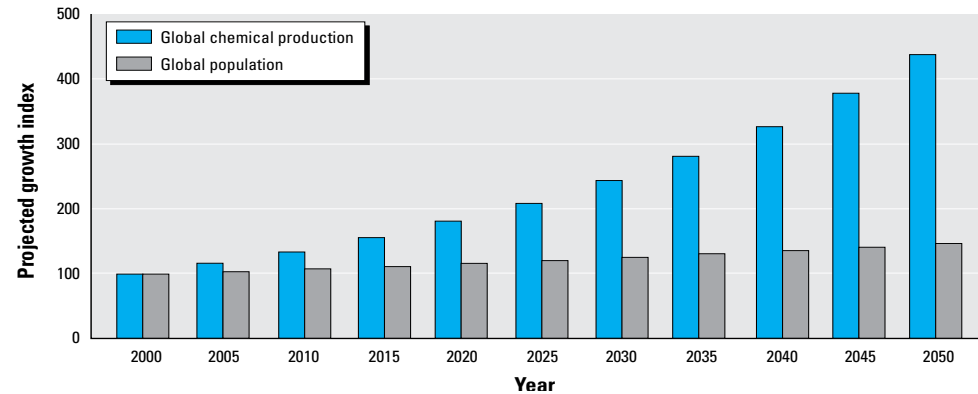
Outline

- Emerging infections as a global challenge
- The Case of Zika Emerging in Puerto Rico
- From Rubella Vaccine to an Effective Zika Elimination Strategy



Global Chemical Production, 2000-2050

Another Source of Emerging Diseases



- In the US alone
 - about 83,000 chemical substances on sale since 1979
 - about 62,000 were in commercial use in 1976 when the Toxic Substances Control Act was enacted.
 - Few chemicals have been evaluated for safety or teratogenicity

Source: Environmental Health Perspectives • volume 117 | number 8 | Page 1203 August 2009

The Concept of Emerging Diseases...

Special Issue

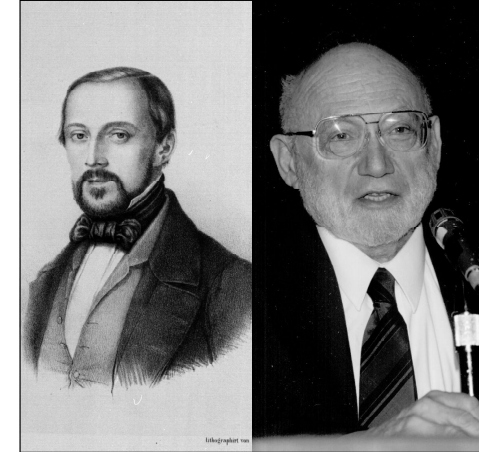
Emerging Infectious Diseases: A Brief Biographical Heritage

D. Peter Drotman

Centers for Disease Control and Prevention, Atlanta, Georgia, USA

The concept that infectious (and other) diseases emerge and reemerge is not new, and neither is the search for causes of disease emergence. However, societies frequently overlook or forget that microbes evolve, adapt, and emerge in response to nonmicrobial and even nonbiologic changes in the physical and social environment. Sometimes we need to be rudely

Even though Virchow was working before the germ theory of disease was accepted, at a time when disease causation was highly debated and microbes were not well described, he seems to have correctly diagnosed typhus (or possibly relapsing fever) as the cause of the Silesian epidemic (1). Even though Virchow's diagnosis cannot be confirmed, it is consistent with clinical



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Zika: History of Discovery, 1947



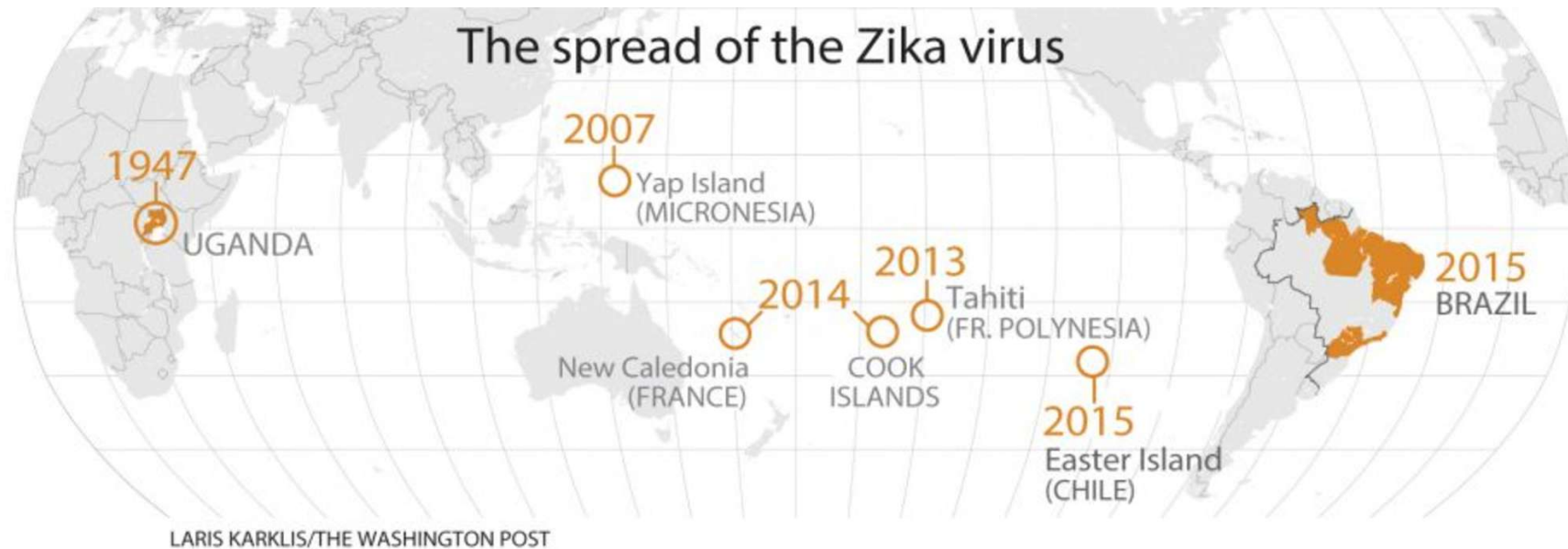
FROM:

<http://www.popsci.com/zika-virus-making-an-epidemic>

Accessed March 1, 2016

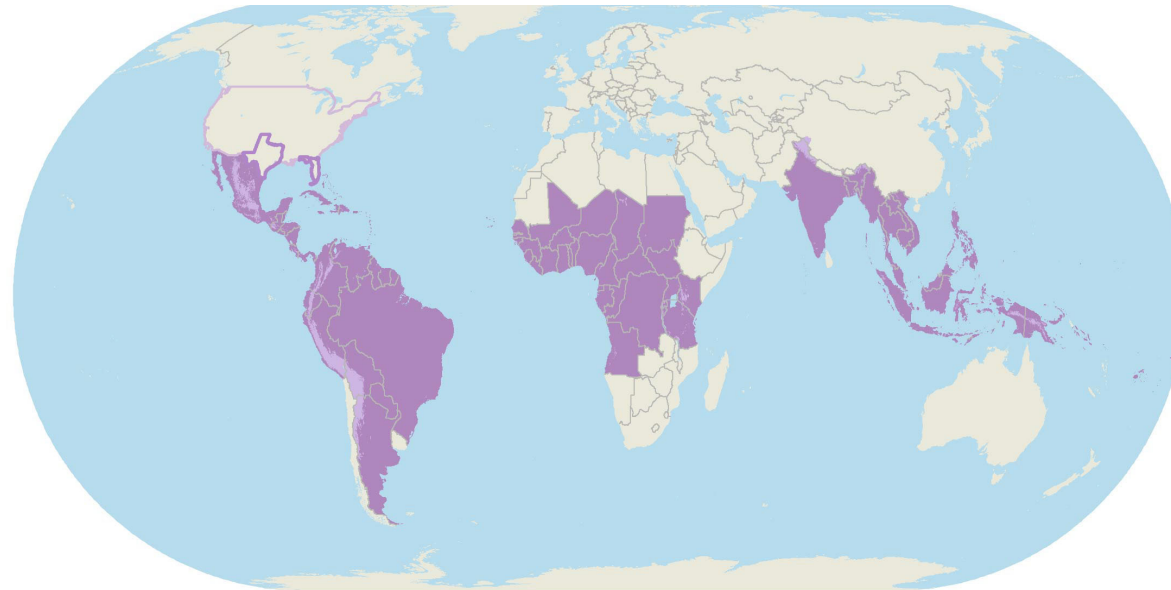
- Zika is a virus of the same family as dengue and yellow fever
- Transmitted by mosquitos, *Aedes aegyptti*, and other *Aedes* species, the same vector that also transmits dengue, chikungunya, and yellow fever
- Zika is a flavivirus

How has Zika Spread Around the World?





FROM: <http://www.popsci.com/zika-virus-making-an-epidemic>, Accessed: March 1, 2016




Countries with Active Zika Transmission, CDC, 2017



United States areas

-  State Reporting Zika
-  No Known Zika

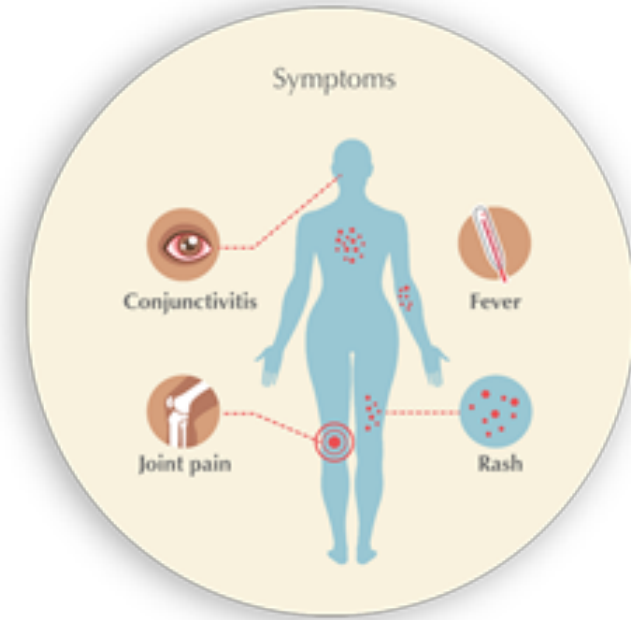
International areas

-  Area with risk of Zika
-  Area with minimal risk of Zika
-  No Known Zika

Source: CDC <https://wwwnc.cdc.gov/travel/files/zika-areas-of-risk.pdf>

Clinical Symptoms

- Mild or no symptoms
- Rash, headache, joint pain, red eye (non-purulent conjunctivitis)
- 3-12 days post-infection
- Last for about one week
- Supportive treatment only
- Persistent in semen and eye
- **4 of 5 infected are asymptomatic**



Source: CDC, 2016



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Congenital Zika Syndrome



Clinical Review & Education

JAMA Pediatrics | Review

Characterizing the Pattern of Anomalies in Congenital Zika Syndrome for Pediatric Clinicians

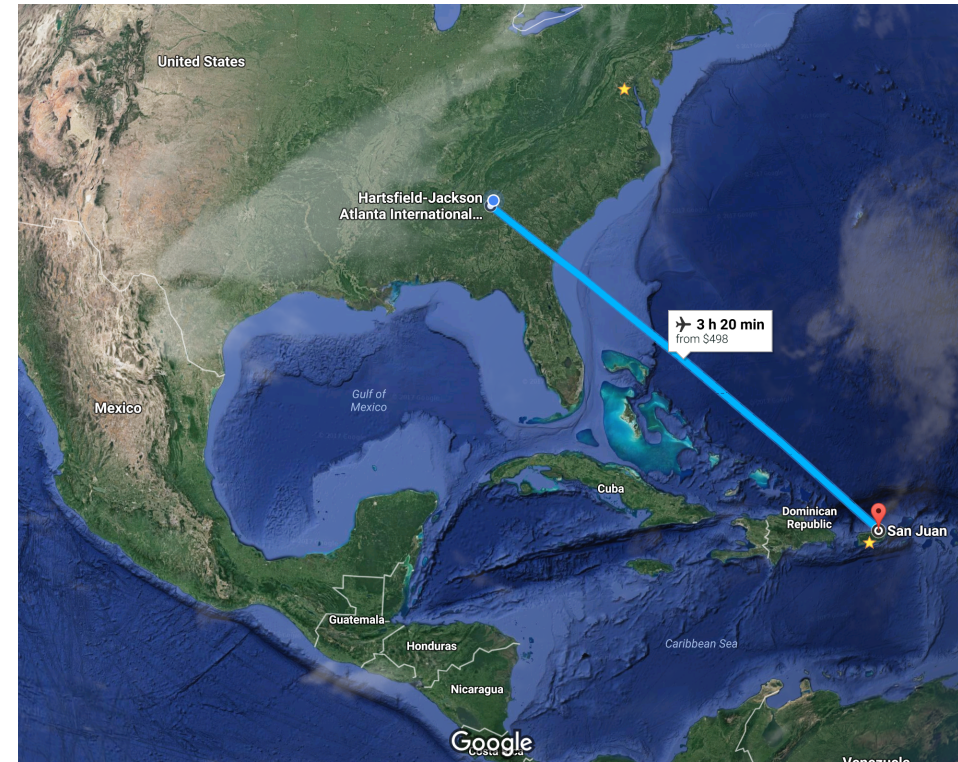
Cynthia A. Moore, MD, PhD; J. Erin Staples, MD, PhD; William B. Dobyns, MD; André Pessoa, MD;
Camila V. Ventura, MD; Eduardo Borges da Fonseca, MD, PhD; Erlane Marques Ribeiro, MD, PhD;
Liana O. Ventura, MD; Norberto Nogueira Neto, MD; J. Fernando Arena, MD, PhD; Sonja A. Rasmussen, MD, MS



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Where is Puerto Rico?

- Located in the West Indies, next to Dominican Republic and Haiti
- United States Territory since 1898
- Has a population of about 3.4 million
- Endemic area for dengue, chikungunya, and now Zika
- A major portal of entry for emerging tropical diseases in US soil



Zika Virus Local Transmission, Puerto Rico, 2015-2016

Morbidity and Mortality Weekly Report

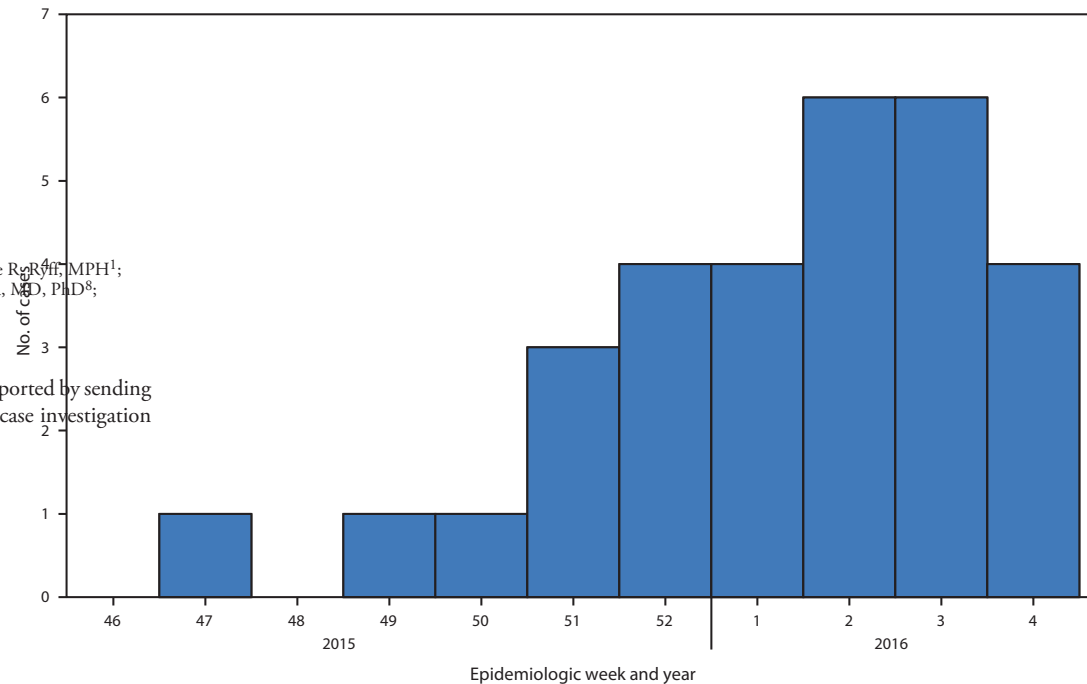
Local Transmission of Zika Virus — Puerto Rico, November 23, 2015–January 28, 2016

Dana L. Thomas, MD^{1,2}; Tyler M. Sharp, PhD³; Jomil Torres, MS¹; Paige A. Armstrong, MD⁴; Jorge Munoz-Jordan, PhD³; Kyle Reynolds, MPH¹; Alma Martinez-Quinones, MPH⁵; José Arias-Berrios, MD⁶; Marrielle Mayshack^{1,7}; Glenn J. Garayalde, MD⁸; Sonia Saavedra, MD, PhD⁸; Carlos A. Luciano, MD⁶; Miguel Valencia-Prado⁵; Steve Waterman, MD³; Brenda Rivera-García, DVM¹

On February 12, 2016, this report was posted as an MMWR Early Release on the MMWR website (<http://www.cdc.gov/mmwr>).

When a clinician suspected Zika virus disease were reported by sending a serum specimen with a modified dengue case investigation

FIGURE 1. Zika virus disease cases* (N = 30), by week of onset of patient's illness — Puerto Rico, November 23, 2015–January 28, 2016



Source: <https://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm6506e2.pdf>



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Public Health Response to Zika, Puerto Rico, 2016

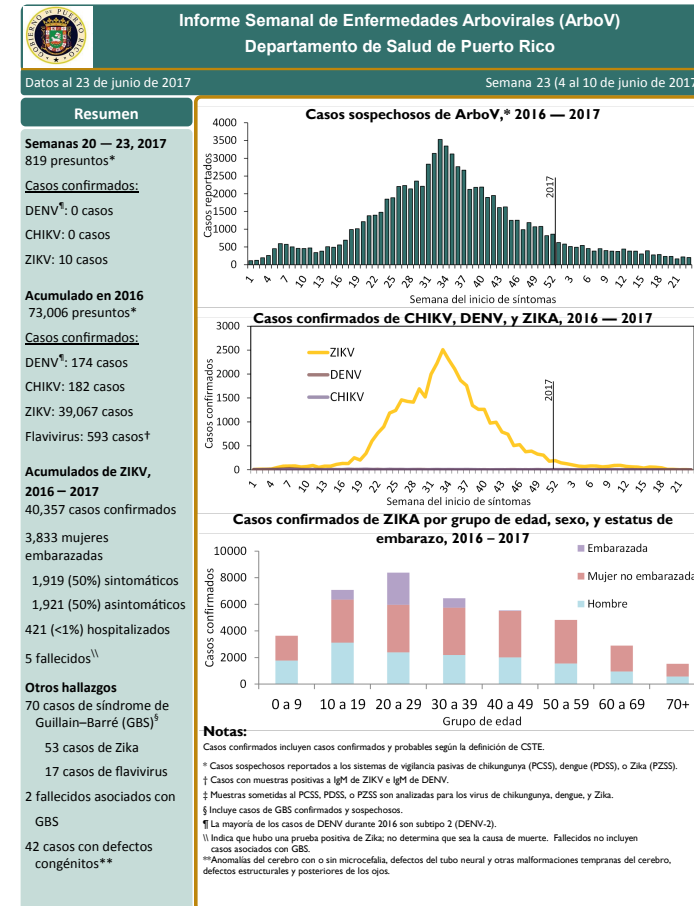
- Monitoring of Zika
 - Establishing Laboratory capacity
 - Monitoring all Zika-positive pregnant women
 - Monitoring microcephaly & other birth defects
 - Track Guillain-Barré syndrome cases
- Implement Risk Reduction Strategies
 - Community Engagement
- Establish a Vector Control Program



Monitoring Arboviral Infections: Puerto Rico, 2016-2017

Puerto Rico established an arboviral surveillance with weekly reports of presumptive and confirmed cases of Zika, dengue and chikungunya

Source:
<https://www.salud.gov.pr/Estadisticas-Registros-y-Publicaciones/Informes%20Arbovirales/Reporte%20ArboV%20semana%2011-2017.pdf>



Zika Response, Laboratory Capacity, Puerto Rico 2016

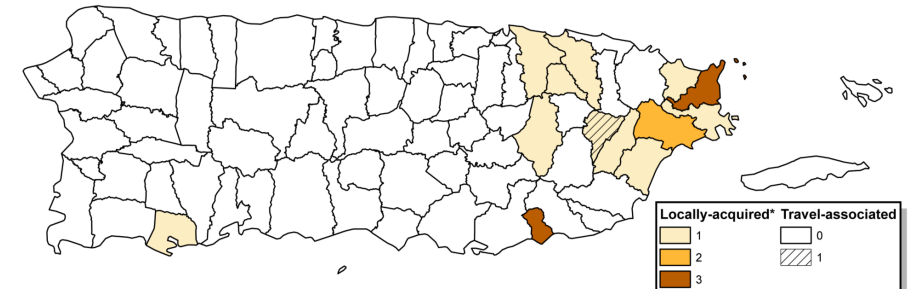
- What was needed?
 - Sufficient capacity to
 - Test Zika samples
 - From 50 to 2000 tests per week
 - Track testing, results, and reporting
 - Trained laboratory and support staff
 - Sufficient laboratory supplies
 - PCR & IgM kits



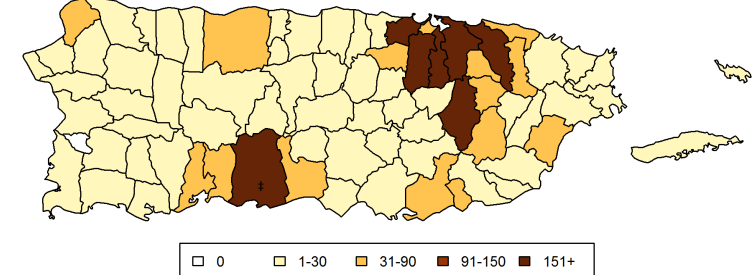
Puerto Rico: Zika in Pregnancy 2016-2017

- Confirmed Cases: 40,357 → ~200,000 infected
- Pregnant Women: 3,833
 - 1,919 (50%) Symptomatic → ~9,500 infected
 - 1,921 (50%) Asymptomatic → ~20% detected
- Guillain-Barré Cases: 70 (53 confirmed Zika, 17 flavivirus)
 - 2 deaths
- Congenital Defects
 - 42 cases

Casos confirmados (N=18) de ZIKV, Semanas 47-2

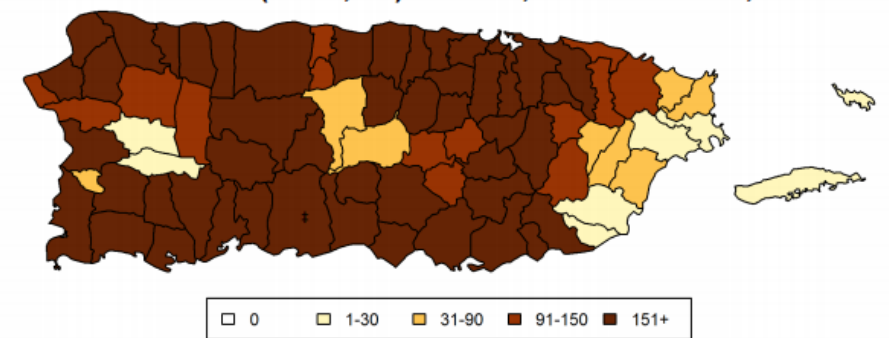


Casos confirmados (n = 4,986)[†] de ZIKV, 2015-semana 27, 2016



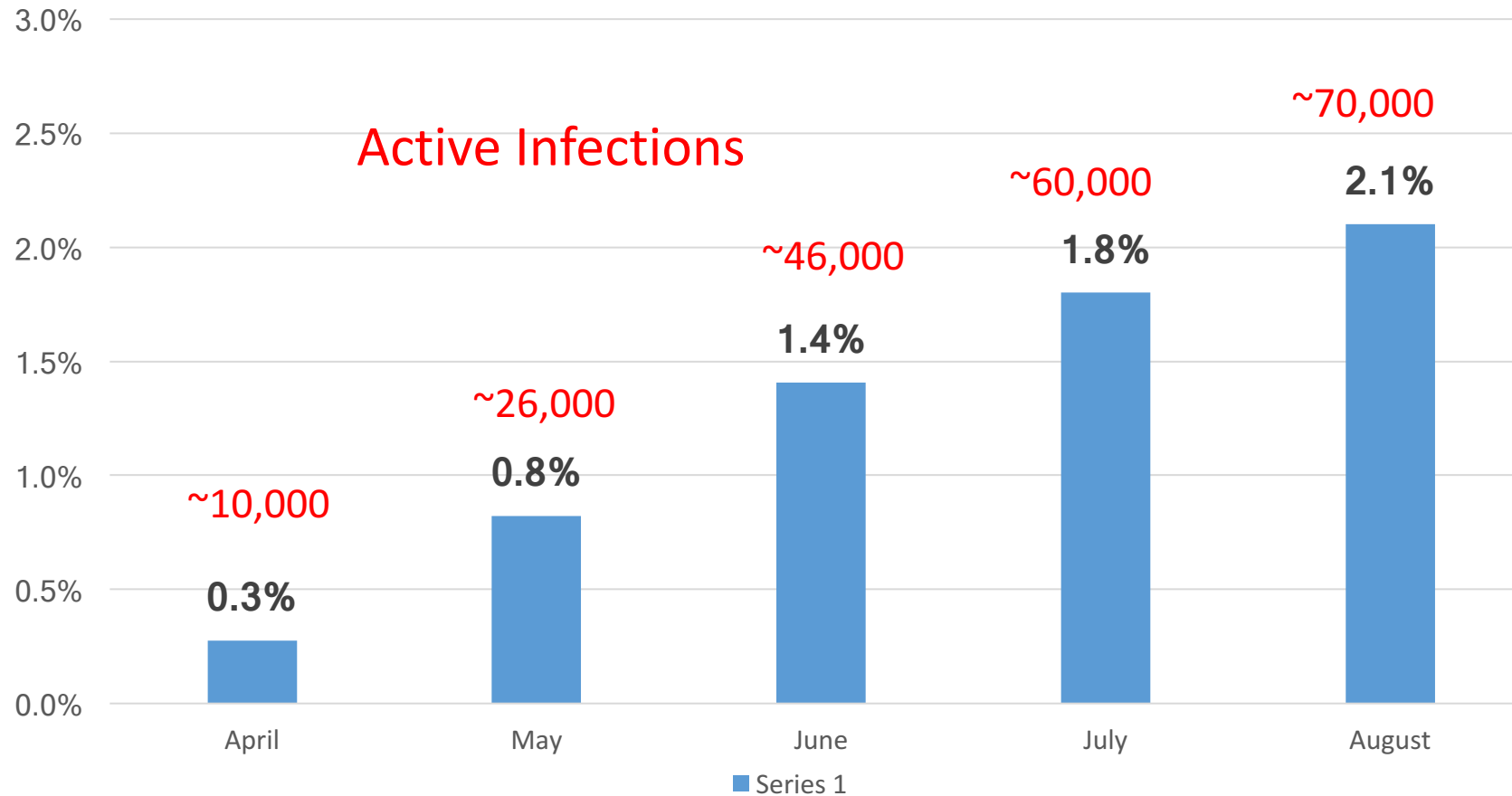
datos al sistema de vigilancia de chikuneunva (PCSS), dengue (PDSS), o Zika (PZSS).

Casos confirmados (n = 29,755)[†] de ZIKV, 2015-semana 40, 2016



Zika Response: Protection of Blood Supply

Blood Donors Surveillance for Zika, Puerto Rico, 2016



Source: CDC, MMWR, 2016



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Public Health Response to Zika, Puerto Rico, 2016

- Monitoring of Zika
 - Establishing Laboratory capacity
 - Need to surge capacity to >2,000 tests per week
 - Monitoring all Zika-positive pregnant women
 - Monitoring microcephaly & other birth defects
 - Track Guillain-Barré syndrome cases
- Implement Risk Reduction Strategies
 - Community Engagement
- Establish a Vector Control Program



Zika Community Education: Puerto Rico, 2016

- Need to convey message of urgency about Zika and particularly for pregnant women
 - How to be protected against mosquito bites?
 - CDC Zika kits
 - Clothing with long sleeves and pants
 - Screens in all doors and windows in the home
 - Use of air-conditioning to sleep
 - Remove mosquito breeding sources

CDC's Response to **Zika**

PREGNANT AND LIVING IN AN AREA WITH ZIKA?

Zika Prevention Kit for Pregnant Women

Your Zika Prevention Kit contains products to help prevent the spread of Zika. Please use these items to protect yourself against Zika virus. Always follow instructions on the product.



Bed Net

- If your room has mosquitoes in it, sleep under the bed net.
- Mosquitoes can live inside houses and will bite at any time, day or night.



Mosquito Spray

- A mosquito spray, such as the one in the kit, will help keep mosquitoes from biting you.
- Use only EPA-registered mosquito spray like the one in this kit.
- Always follow the directions on the bottle.
- For the spray to work well you will need to put it on again as directed.
- Do not spray under your clothing.



Condoms

- During sex, it is possible to get Zika virus from a partner who has Zika. If you have sex during your pregnancy, you should use condoms the right way every time.
- Condoms can also help prevent HIV and other sexually transmitted diseases.



Standing Water Treatment Tabs

- Use water treatment tabs to kill larvae (mosquito eggs) in standing water around your house, such as in rain buckets. Do not put them in water you drink.
- When used as directed, these tabs will not harm you or your pets (dogs and cats).



Permethrin Spray

- Spray your clothes with the bug spray called permethrin. This will help protect you from mosquito bites.
- Clothes sprayed with permethrin will protect you for 6 weeks. You can wash your clothes up to 6 times during the 6 weeks and the permethrin will still protect you.
- Make sure to read the directions on the bottle.
- Do not spray permethrin on your skin.

www.cdc.gov/zika



Zika Community Education: Puerto Rico, 2016 Challenges

- CDC Zika kits
 - Condom use
 - Permethrin resistance
- Cost of screens in households and air conditioning
- Public Perception
 - Is there a problem with Zika?
 - Zika is mostly a silent epidemic with 80% asymptomatic
- Impact on Tourism & Economy

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www.cdc.gov/zika



Public Health Response to Zika, Puerto Rico, 2016

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Impact on Tourism and the Economy

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WABE 90.1

the **two-way**

INTERNATIONAL

Major League Baseball Cancels Series In Puerto Rico Due To Zika Concerns

May 7, 2016 · 11:09 AM ET

MERRIT KENNEDY



SOURCE:

<http://www.npr.org/sections/thetwo-way/2016/05/07/477147993/major-league-baseball-cancels-series-in-puerto-rico-due-to-zika-concerns>



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From Monitoring and Containment to Prevention: Countermeasures

Zika Countermeasures: Research and Development

- Research on biology of Zika infection
- Vaccine development
- Therapeutics
- Diagnostics
- Product development
 - Novel Vector Control Strategies

Rubella infection During Pregnancy causes Congenital Rubella Syndrome

- Rubella
 - A very mild disease in adults
 - First human infection to be recognized as a teratogen
 - Congenital Rubella Syndrome
 - Triad of:
 - Sensorineural Deafness
 - Congenital Heart Disease
 - Cataracts



Dr. Norman McAlister Gregg
1892-1966

Source: <https://www.mja.com.au/journal/2002/177/11/greggs-congenital-rubella-patients-60-years-later>



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Congenital Rubella Syndrome

Clinical Findings

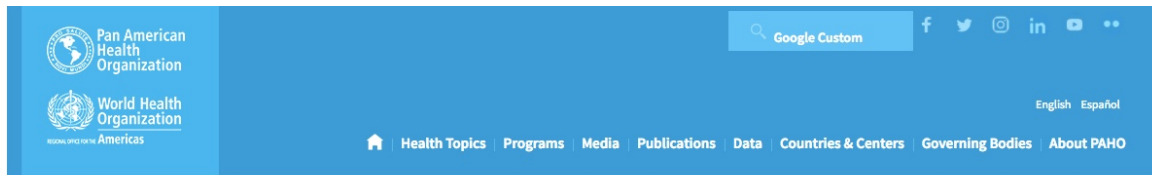
- Newborn disease
 - Meningo-encephalitis
 - Jaundice
 - Purpura
 - Thrombocytopenia
 - Hepatosplenomegaly
 - Low birth weight
- Microcephaly
- Glaucoma
- Cataracts
- Pigmentary retinopathy
- Congenital Heart Disease
 - PDA
 - Pulmonic Stenosis
- Radioluscent bone disease



Source: <https://www.cdc.gov/rubella/about/photos.html#>



Rubella Elimination: From 1963 to 2016



Region of the Americas is declared free of measles

Washington, D.C., 27 September 2016 (PAHO/WHO) – The Region of the Americas is the first in the world to have eliminated measles, a viral disease that can cause severe health problems, including pneumonia, brain swelling and even death. This achievement culminates a 22-year effort involving mass vaccination against measles, mumps and rubella throughout the Americas.

The declaration of measles' elimination was made by the International Expert Committee for Documenting and Verifying Measles, Rubella, and Congenital Rubella Syndrome Elimination in the Americas. The announcement came during the 55th Directing Council of the Pan American Health Organization/World Health Organization (PAHO/WHO), which is currently underway and is being attended by ministers of Health from throughout the Americas.

http://www.paho.org/hq/index.php?option=com_content&view=article&id=12528%3Aregion-americas-declared-free-measles

COMMENTARY

The Eradication of Rubella

Stanley A. Plotkin, MD

Michael Katz, MD

José F. Cordero, MD, MPH

DURING 1963 TO 1964, A PANDEMIC OF RUBELLA SWEEPED across Europe and the United States, leaving in its wake at least 20 000 affected infants in this country alone.¹ During the epidemic an expanded congenital rubella syndrome (CRS) was described, involving not only the classic triad of cataracts, cardiac abnormalities, and deafness, but also encephalitis, wasting, hepatitis, pneumonia, endocrinopathies, and other sequelae. This disaster supervened just after the first isolation of rubella virus in cell

The CRS is still an important cause of birth defects and disabilities in developing countries. An extensive review by Cutts et al¹⁰ showed convincingly that CRS occurs on all continents and in persons of all races and socioeconomic levels. Seroprevalence studies have demonstrated that women in many developing countries have low seroimmunity to rubella, particularly in rural areas and islands.¹¹

Fortunately, as was the case previously with poliomyelitis and measles, the Pan American Health Organization has recognized the rubella problem and has taken action. Laboratory testing of suspected measles cases during 1996 and 1997 in several Latin American countries revealed that at least one third were actually rubella. Armed with that information, and bearing in mind that both MMR and measles-rubella vaccines are

Source: *JAMA*. 1999;281(6):561-562. doi:10.1001/jama.281.6.561



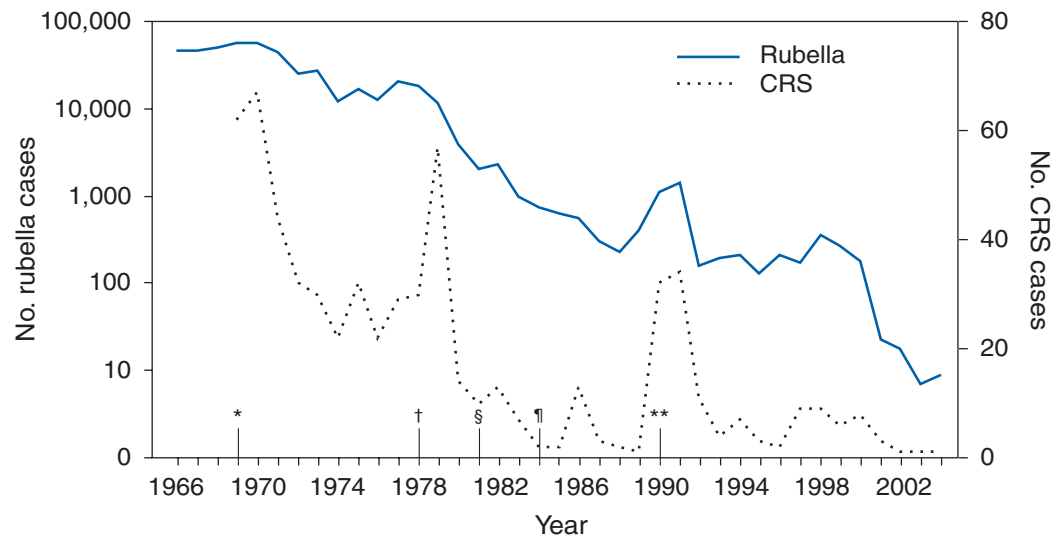
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Congenital Rubella Syndrome Elimination, United States, 2005

280

MMWR

FIGURE. Number of reported cases of rubella and congenital rubella syndrome (CRS), by year, and chronology of rubella vaccination recommendations by the Advisory Committee on Immunization Practices — United States, 1966–2004



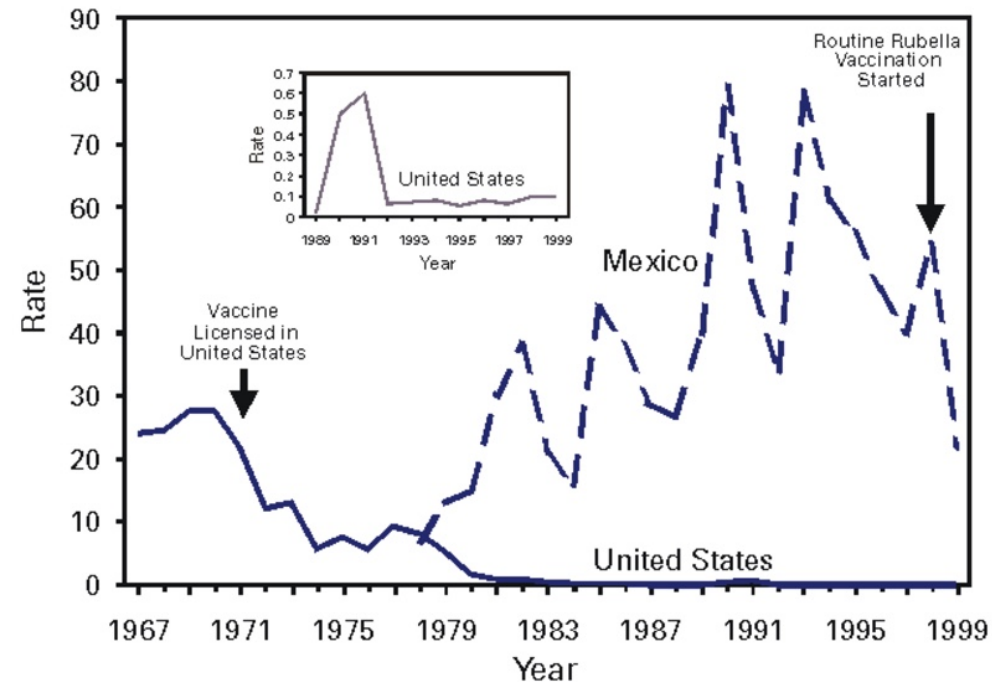
Source: MMWR. March 25, 2005 / Vol. 54 / No. 11



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Rubella Elimination, The Americas, 1967 -1999

FIGURE 2. Rubella incidence rates*, by year — Mexico, 1978–1999, and United States, 1967–1999



Source: <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm4946a3.htm>



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Rubella Elimination, Americas Region, 2015

The screenshot shows the website header with logos for the Pan American Health Organization and the World Health Organization Regional Office for the Americas. A search bar and social media icons are also present. The main content area features a blue header for the article, a sub-header with social media icons, and a main headline. Below the headline is a sub-headline and a paragraph of text. To the right, there is a section for the 70th WHO meeting and a list of WHO news items. A sidebar on the left contains a 'Media Center' menu with various links.

Media Center

- Main Page
- Press Releases
- Web Bulletins
- Country News
- Fact sheets
- Infographics
- Champions of Health
- Public Health Heroes
- Multimedia
- Speakers Bureau

Press Contacts

Leticia Linn

Americas region is declared the world's first to eliminate rubella

Historic achievement follows similar "firsts" against smallpox in 1971 and polio in 1994

Washington, D.C., 29 April 2015 (PAHO/WHO) — The Americas region has become the first in the world to be declared free of endemic transmission of rubella, a contagious viral disease that can cause multiple birth defects as well as fetal death when contracted by women during pregnancy.

This achievement culminates a 15-year effort that involved widespread administration of the vaccine against measles, mumps and rubella (MMR) throughout the Western Hemisphere. The announcement comes as 45 countries and territories of the Americas are participating in the 13th annual Vaccination Week in the Americas (April 25 to May 2).

70th WHA



[Link to 70th WHA website](#)

WHO News

- Statement from UNICEF Executive Director Anthony Lake and WHO Director-General Margaret Chan on the cholera outbreak in Yemen as suspected cases exceed 200,000
- Abuse of older people on the rise – 1 in 6 affected
- WHO Director-General elect welcomes new funding for polio eradication



Approaches to Zika Elimination

Zika Vaccine : Research and Development

- Vaccines
 - Zika Purified Inactivated Virus (ZPIV)
 - Inactivated Zika virus with a Japanese encephalitis protein shell
 - Moderna Zika Vaccine
 - lipid nanoparticle (LNP) encapsulated modified mRNA vaccine encoding wild-type or variant ZIKV structural gene
 - GeoVax & UGA
 - VLPs—virus-like particles—mimic a live virus but do not contain genetic material; they cannot replicate or cause infection, yet they elicit a strong immune response in the cells of the person being vaccinated.
 - Others

Key Attributes of Candidate Zika Vaccines

- Highly effective > 90% efficacy
- Prevent infection during pregnancy
- Have the potential to control and eliminate Zika

Experience with Dengue Vaccine

EFFICACY BY SEROTYPE:

RANGES:

42.3% TO 77.7%

50.2% TO 80.9%

Table 3. Serotype-Specific Vaccine Efficacy.

Variable	Vaccine Group			Control Group			Vaccine Efficacy (95% CI)
	Cases	Person-Yr at Risk	Incidence Density (95% CI)	Cases	Person-Yr at Risk	Incidence Density (95% CI)	%
	no.	no.	no./100 person-yr	no.	no.	no./100 person-yr	%
Modified per-protocol analysis*							
Serotype 1	66	12,478	0.5 (0.4–0.7)	66	6,196	1.1 (0.8–1.4)	50.3 (29.1–65.2)
Serotype 2	58	12,495	0.5 (0.4–0.6)	50	6,219	0.8 (0.6–1.1)	42.3 (14.0–61.1)
Serotype 3	43	12,514	0.3 (0.2–0.5)	82	6,213	1.3 (1.1–1.6)	74.0 (61.9–82.4)
Serotype 4	18	12,522	0.1 (0.1–0.2)	40	6,206	0.6 (0.5–0.9)	77.7 (60.2–88.0)
Unknown	6	12,540	<0.1 (0.0–0.1)	3	6,268	<0.1 (0.0–0.1)	0.0 (–517.8–78.6)
Intention-to-treat analysis							
Serotype 1	99	27,016	0.4 (0.3–0.4)	109	13,434	0.8 (0.7–1.0)	54.8 (40.2–65.9)
Serotype 2	84	27,035	0.3 (0.2–0.4)	84	13,461	0.6 (0.5–0.8)	50.2 (31.8–63.6)
Serotype 3	55	27,060	0.2 (0.2–0.3)	106	13,459	0.8 (0.6–1.0)	74.2 (63.9–81.7)
Serotype 4	32	27,063	0.1 (0.1–0.2)	83	13,442	0.6 (0.5–0.8)	80.9 (70.9–87.7)
Unknown	15	27,079	<0.1 (0.0–0.1)	14	13,514	0.1 (0.1–0.2)	46.5 (–19.6–75.9)

* The modified per-protocol analysis was performed at least 28 days after the third injection in all participants who had received three doses, regardless of protocol deviations.



Efficacy of a Tetravalent Dengue Vaccine in Children in Latin America

Luis Villar, M.D., Gustavo Horacio Dayan, M.D., José Luis Arredondo-García, M.D., Doris Maribel Rivera, M.D., Rivaldo Cunha, M.D., Carmen Deseda, M.D., Humberto Reynales, M.D., Maria Selma Costa, M.D., Javier Osvaldo Morales-Ramírez, M.D., Gabriel Carrasquilla, M.D., Luis Carlos Rey, M.D., Reynaldo Dietze, M.D., Kleber Luz, M.D., Enrique Rivas, M.D., Maria Consuelo Miranda Montoya, M.D., Margarita Cortés Supelano, M.D., Betzana Zambrano, M.D., Edith Langevin, M.Sc., Mark Boaz, Ph.D., Nadia Tornieporth, M.D., Melanie Saville, M.B., B.S., and Fernando Noriega, M.D., for the CYD15 Study Group*



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Aedes Aegypti elimination in the Americas

- *Aedes aegypti* have been eliminated in the Americas at least three times, even before availability of DDT



FRED SOPER (1893 – 1977)

Lead elimination of *Aedes aegypti* in the Americas during the first half of the 20th Century. Many of his approaches in vector control are used today.

Hawaii is planning to eliminate *Aedes aegypti*

Source: Wikipedia, 2017



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Zika Response: Vector Control, Puerto Rico, 2016- 2017

- There is a need to address vector control as a strategy to reduce transmission of Zika, dengue, and chikungunya
- Strategies should include:
 - Source reduction
 - Integrated control management
 - Novel approaches
 - All based on strong and well organized community engagement



Screwworm elimination in the Americas, 2016

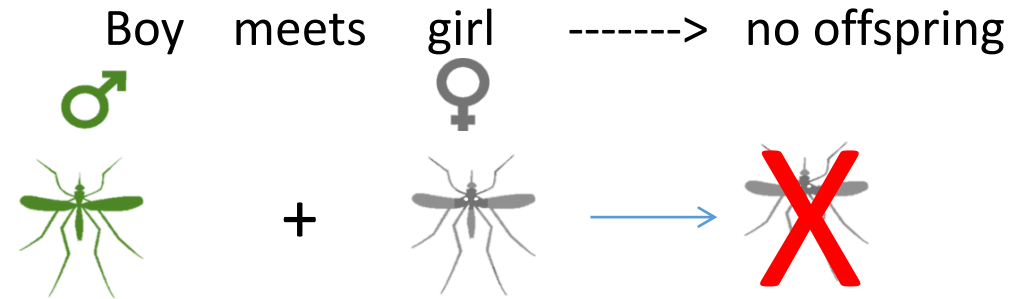


Source:
<https://www.ars.usda.gov/oc/timeline/worm/>





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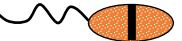
Sterile Insect Techniques (SIT) for targeted mosquito elimination



Types of SIT

Irradiation -> random DNA changes -> Dominant Lethal Mutations 

Genetic Engineering -> engineered DNA changes -> Dominant Lethal Mutations 

Wolbachia -> Bacterial Infection -> Cytoplasmic Incompatibility 

Key Points

- Zika is one of many emerging diseases the world would face in this century.
- Preparedness for emerging infections must be a priority
- There are lessons to be learned from Zika emergence and from Rubella elimination
- Control and elimination of Zika to prevent Congenital Zika Syndrome is a complex proposition that would require multiple strategies

Zika: The Road Ahead

- Zika Emergence is a call to:
 - Strengthen public health infrastructure at the local, state, national and global levels
 - Expand and strengthen collaboration between all sectors of community life including inserting public health in social media
 - Connect and speed up basic science, vaccine and product development and its translation to public health practice

Zika: A Reflexion

- It was once said that the moral test of government is how that government treats those who are in the dawn of life, the children; those who are in the twilight of life, the elderly; and those who are in the shadows of life, the sick, the needy and the handicapped.
- <https://www.brainyquote.com/quotes/quotes/h/huberthhu163688.html>



Thank you!

!Gracias!

