

CHIKUNGUNYA VACCINES

**ACIP Meeting
June 23, 2022**

**Beth Bell, MD, MPH
Chair, ACIP Chikungunya Vaccines Work Group**

Background to formation of Chikungunya Vaccines Work Group

- No chikungunya vaccine ever licensed in United States or globally
- Multiple chikungunya vaccines in development
- One manufacturer planning to submit a BLA to FDA during 2022
 - Licensure possible during 2023
- Work Group formed in May 2022

Purpose of Chikungunya Vaccines Work Group

- To review and evaluate data on chikungunya disease, epidemiology, and vaccines
- To develop policy options for ACIP's consideration for U.S. persons at risk of chikungunya, including
 - Travelers
 - Residents of U.S. territories and states with, or at risk of, transmission

Terms of Reference for Chikungunya Vaccines Work Group

- To review information on chikungunya disease, including outcomes
- To review data on chikungunya epidemiology and burden among U.S. residents, including travelers and persons living in areas at risk for local transmission
- To review data on safety, immunogenicity, and effectiveness of chikungunya vaccines
- To provide evidence-based recommendation options for ACIP
- To identify areas in need of further research for informing potential future vaccine recommendations
- To publish a chikungunya vaccine MMWR Recommendations and Reports document

Chikungunya Vaccines Work Group members

ACIP

Sixun Yang, FDA

Carina Blackmore, Florida Dept Health

Beth Bell, Univ Washington (Chair)

Lesley Dupuy, NIH

Alan Lam, DoD

Wilbur Chen, Univ Maryland

TBD, Puerto Rico

ACIP Liaisons

Margaret Ryan, DoD

CDC Leads

Elizabeth Barnett, ISTM

Steven Schofield, CATMAT

Susan Hills, DVBD (Lead)

James Campbell, AAP

David Shlim, Jackson Hole Travel & Trop Med

Nicole Lindsey, DVBD (Deputy Lead)

Mary Pat Friedlander, AAFP

Nestor Sosa, Uni New Mexico Hospital

Kirsten Vannice, Bill & Melinda Gates Foundation

Ex Officio

Robin Levis, FDA

Invited Consultants

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Mary Wilson, Univ California San Francisco

Chikungunya Vaccines Work Group CDC participants

DVBD

Erin Staples

Ann Powers

Laura Adams

Joshua Wong

NCEZID

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Sarah Guagliardo

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Michael McNeil

Global Immunization Division

Rebecca Casey

Susan Chu

ISD

Elisabeth Velazquez

GRADE/ETR consultants

Doug Campos-Outcalt

Rebecca Morgan

ACIP Secretariat

Jessica MacNeil, NCIRD

Today's session

- Overview of chikungunya disease and vaccines
 - Susan Hills (CDC/NCEZID)
- Plans and timelines for Chikungunya Vaccines Work Group
 - Susan Hills (CDC/NCEZID)

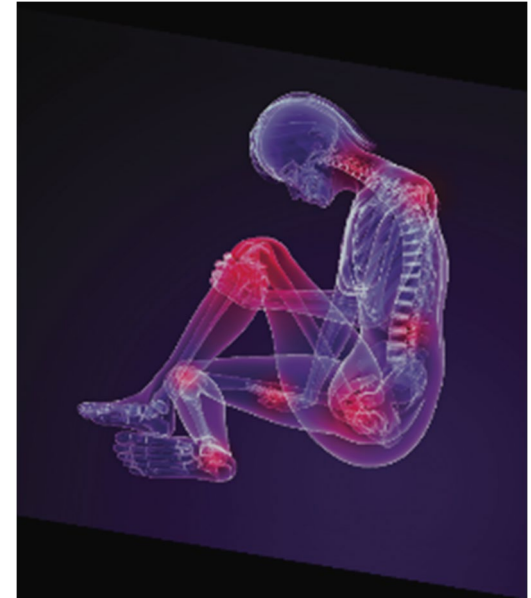


OVERVIEW OF CHIKUNGUNYA AND CHIKUNGUNYA VACCINES

Susan Hills, MBBS, MTH
CDC Lead, Chikungunya Vaccines Work Group
Arboviral Diseases Branch
Division of Vector-Borne Diseases
Fort Collins, Colorado

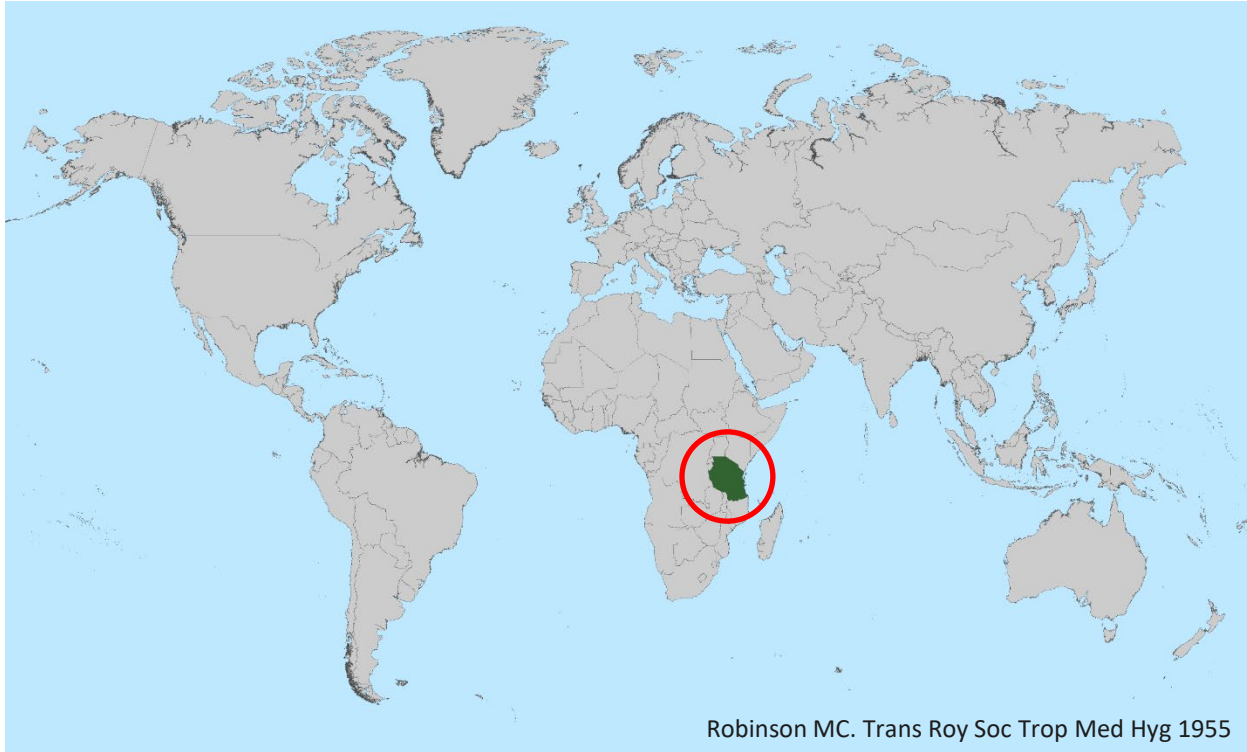
Chikungunya virus disease

- Mosquito-borne disease caused by an *Alphavirus*
- Clinically characterized by acute onset of fever and often severe polyarthralgia
- Has caused large outbreaks with high attack rates
- Outbreaks have occurred in Africa, Asia, Europe, Americas, and islands in the Indian and Pacific Oceans



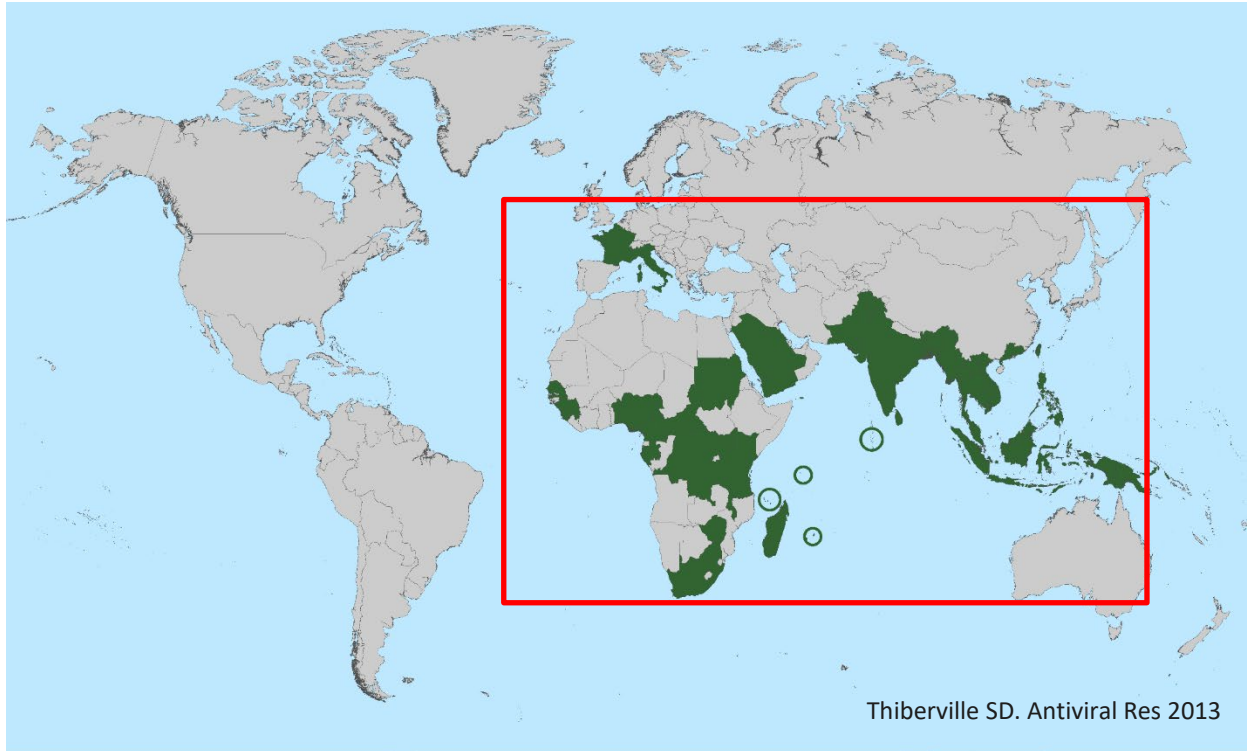
Source: PAHO, 2011. www.paho.org

Chikungunya virus first identified during outbreak of fever and joint pain in Tanzania, 1952–1953

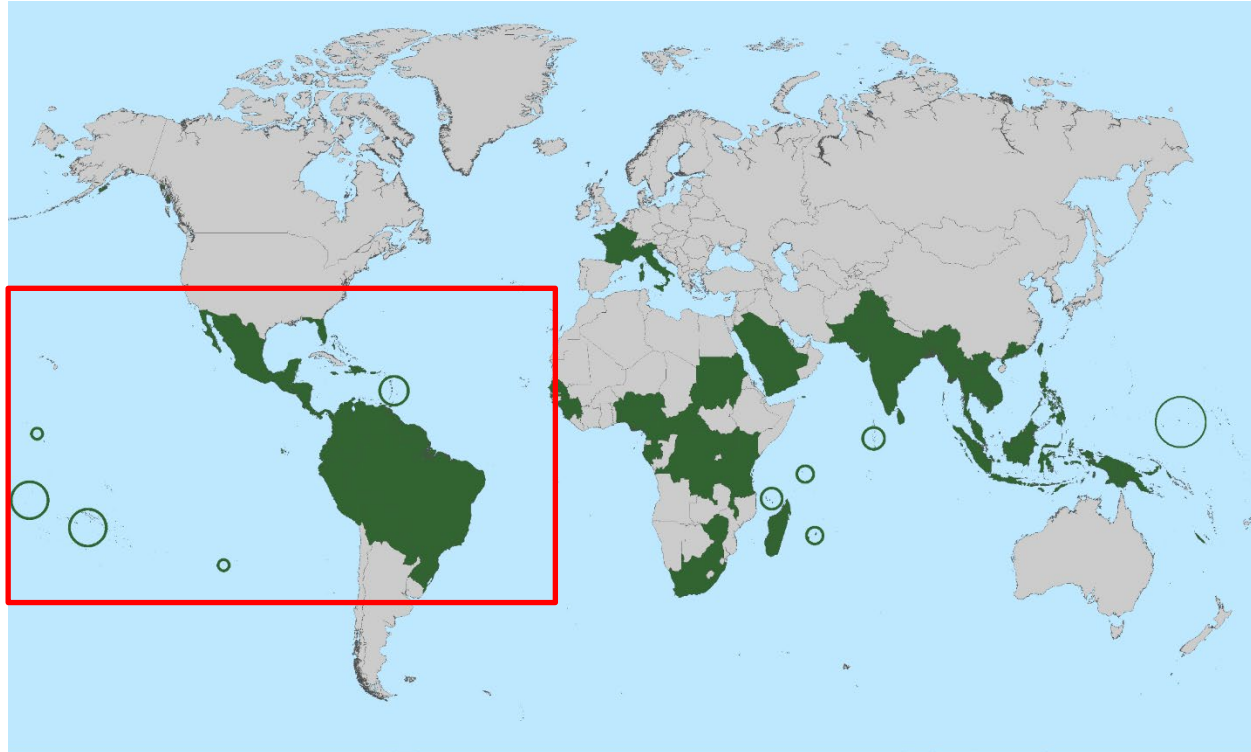


Robinson MC. Trans Roy Soc Trop Med Hyg 1955

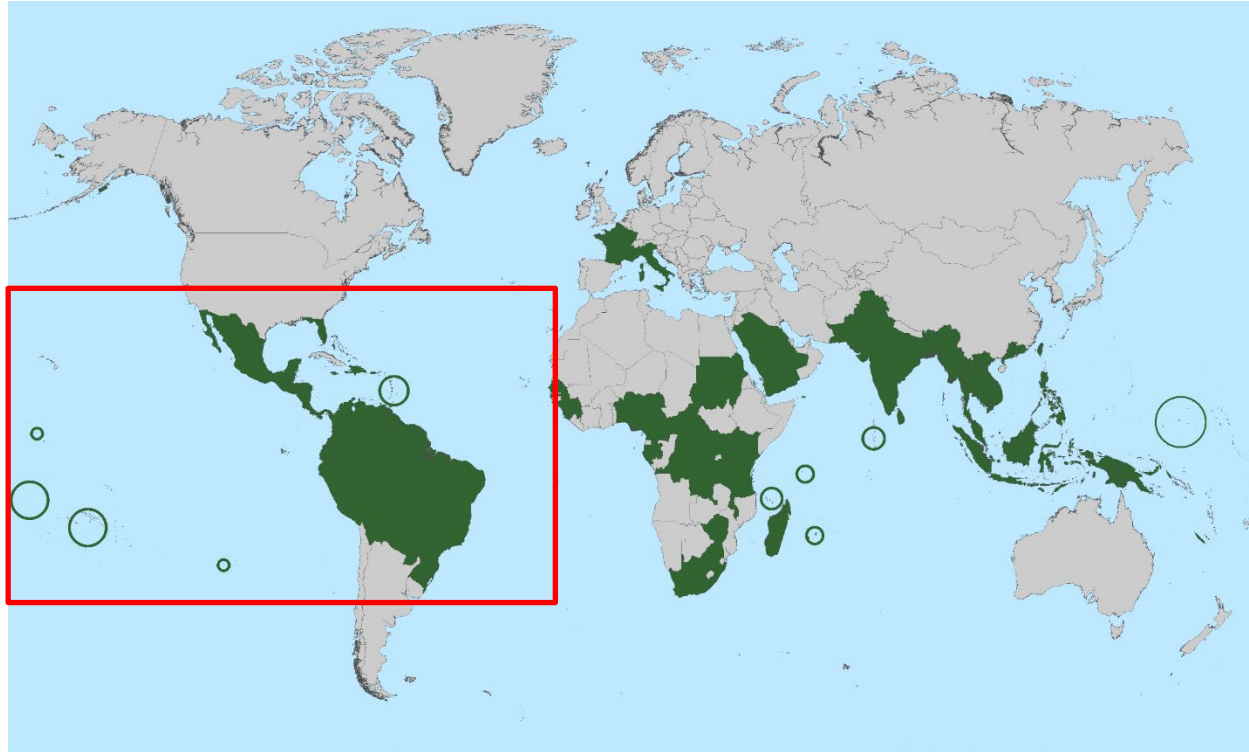
Expansion in area of transmission in Africa, Asia and the Indian Ocean, 1953–2012



Chikungunya virus introduction and spread in the Americas, 2013–2015



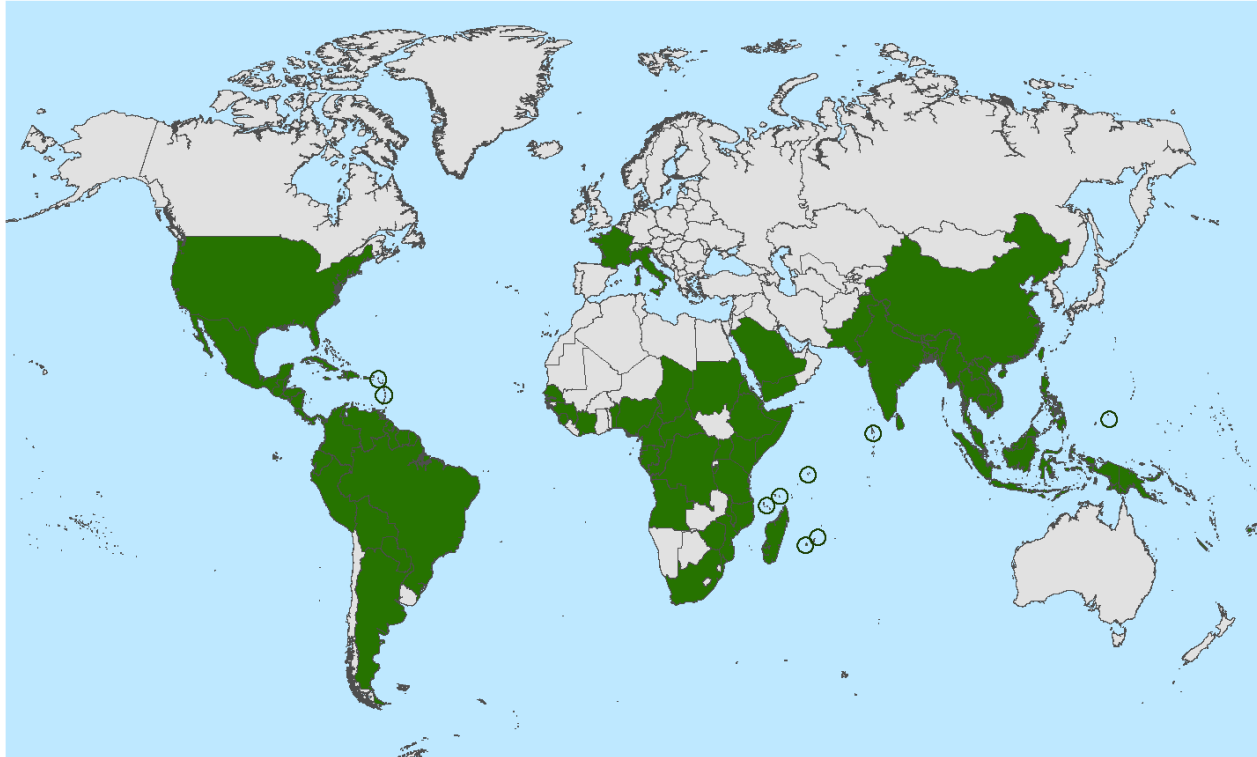
Chikungunya virus introduction and spread in the Americas, 2013–2015



Outbreaks in
US territories

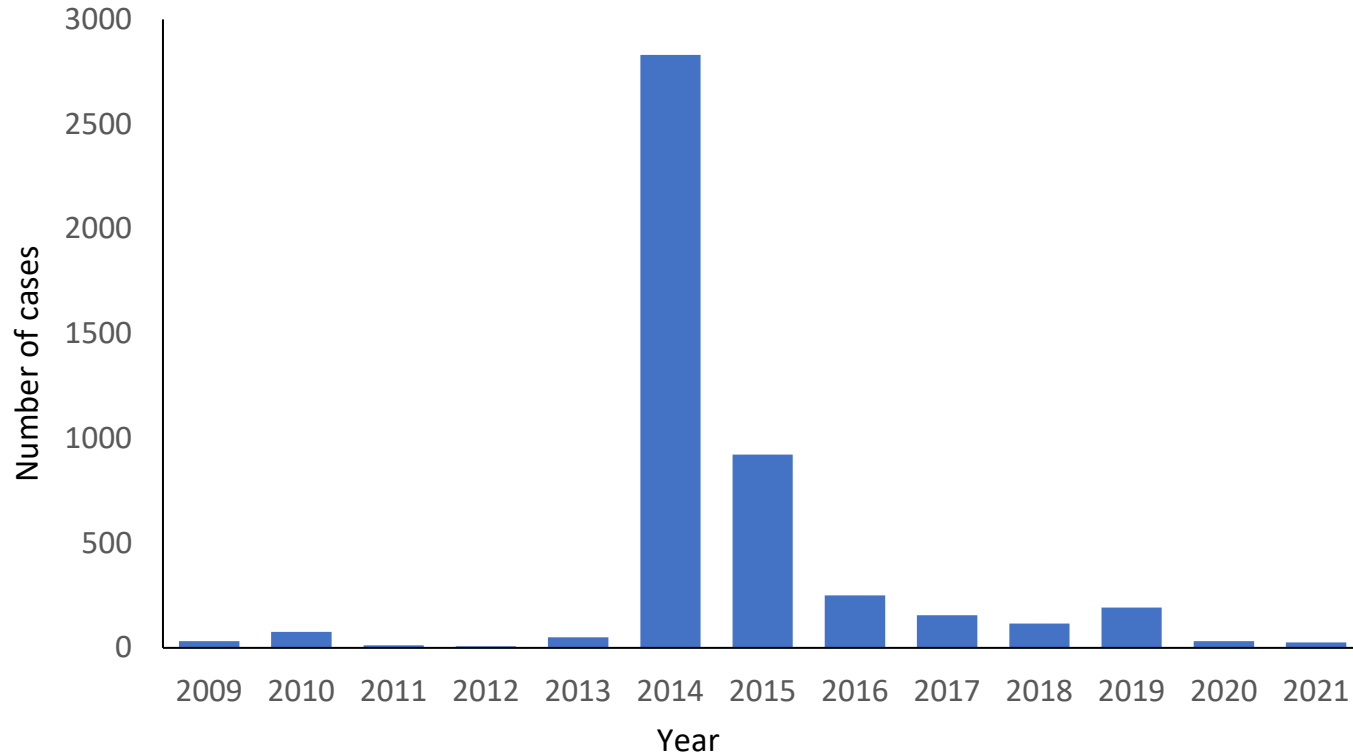
Limited local
transmission
in Florida and
Texas

Countries and territories with past or current transmission of chikungunya virus, 2022



<https://www.cdc.gov/chikungunya/geo/index.html>

Chikungunya cases in US travelers, 2009–2021*



*Based on CDC laboratory and surveillance data

Mosquito vectors



Aedes aegypti



Aedes albopictus

- Daytime biters with peak activity dawn and dusk
- Lay eggs in containers that hold water

Other rare chikungunya virus transmission modes

- Intrauterine
- Intrapartum
- Needlestick injury
- Laboratory exposure

Clinical features of chikungunya

- Incubation period: 3–7 days
- Febrile illness with often severe arthralgia
- Multiple joints involved, typically bilaterally and symmetrically
- Arthralgia most common in hands and feet, can involve more proximal joints
- No specific antiviral treatment



Rare complications

- Myocarditis
- Ocular disease
- Hepatitis
- Acute renal disease
- Severe bullous lesions
- Neurologic disease

Risk factors for severe disease

- Age >65 years
- Underlying medical conditions (e.g., hypertension, diabetes, heart disease)
- Intrapartum transmission
 - Neonatal complications can include neurologic, myocardial, hemorrhagic symptoms

Outcomes

- For many, symptoms resolve in 7–10 days
- Some have ongoing joint pain and prolonged fatigue for months or years
- > 50 studies with variability in results based on
 - Study methodology
 - Duration of follow up
 - Symptom ascertainment
 - Type of cohort
 - Demographics

Risk factors for prolonged symptoms

- Older age
- Severity of acute illness
- Pre-existing joint disease

Prevention of chikungunya

- Protective measures against mosquito bites
- If licensed, chikungunya vaccine

Chikungunya vaccines (Phase III clinical trials)

Manufacturer	Type	Schedule and administration	Status	Notes
Valneva	Live attenuated	1 dose IM	<ul style="list-style-type: none">- Phase III in adults ≥ 18 years completed- Phase III in adolescents (12–17 years) commenced January 2022- Lot-to-lot consistency completed- Expected BLA submission to FDA during second half of 2022	CEPI co-funding
Emergent BioSolutions	Virus-like particle	1 dose IM	<ul style="list-style-type: none">- Phase III in 12–65 years commenced October 2021	

Abbreviations: IM-Intramuscular; BLA-Biologics License Application; FDA-Food & Drug Administration; CEPI-Coalition for Epidemic Preparedness Innovations

Other chikungunya vaccines with support from CEPI

Manufacturer	Type	Schedule and admin	Status	Notes
Merck	Live attenuated measles-vectored	1 dose + booster	- Phase II completed	CEPI co-funding
International Vaccine Institute/ Bharat Biotech	Inactivated whole virus	2-dose	- Phase II/III commenced August 2021	CEPI co-funding

Abbreviations: CEPI - Coalition for Epidemic Preparedness Innovations

Valneva's chikungunya vaccine

- FDA has given the vaccine Breakthrough Therapy designation which allows request for priority review
 - Accelerated approval pathway is 8 months from time BLA submission is received
 - Licensure expected during 2023
- Anticipated initial indication for adults ≥ 18 years
 - Adolescent trial in progress
 - Pediatric trial expected in future

Summary of chikungunya and chikungunya vaccine

- Mosquito-borne disease that can cause large outbreaks
 - In United States, previous outbreaks in territories and limited local transmission in states (i.e., Florida, Texas)
 - For travelers, greatest risk during outbreak periods
- Clinical presentation with fever and severe polyarthralgia with risk for long-term joint symptoms
- One vaccine, manufactured by Valneva, soon to be submitted for licensure
- No chikungunya vaccine previously licensed and no existing ACIP chikungunya vaccine recommendations



NEXT STEPS FOR CHIKUNGUNYA VACCINES WORK GROUP

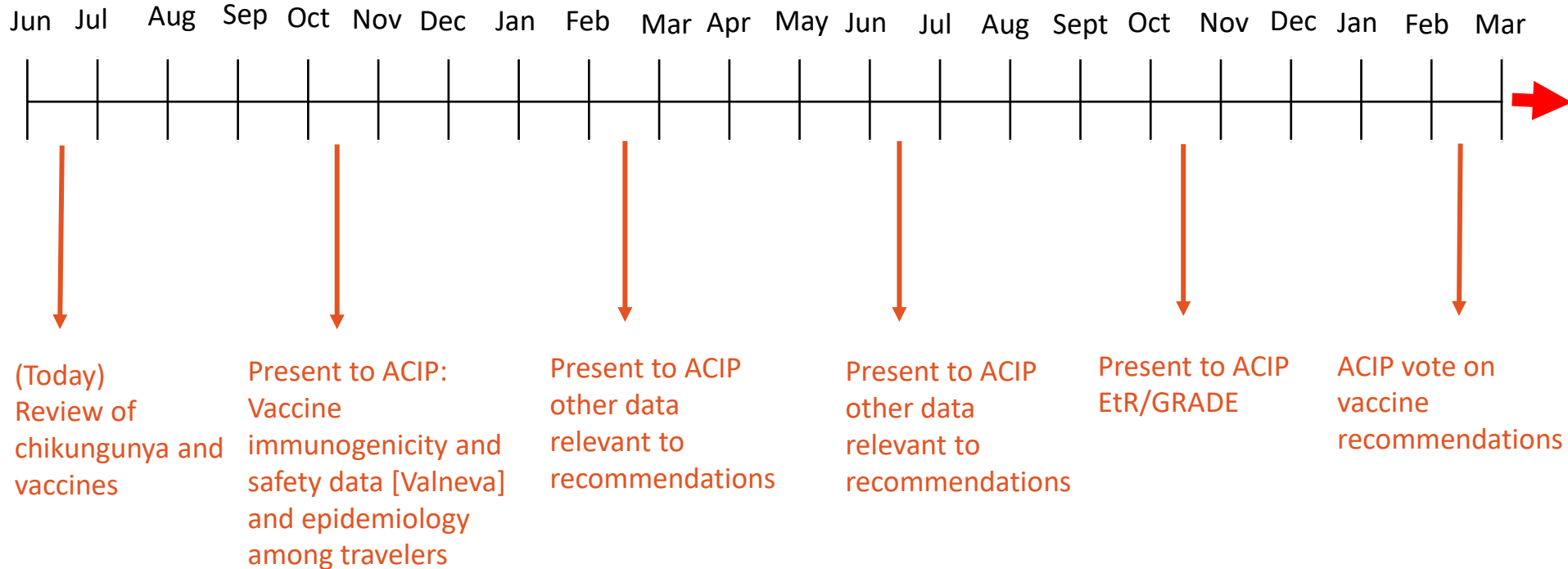
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Work Group timeline (tentative)

2022: *BLA submission*

2023: *Possible licensure*

2024



Future topics

- Epidemiology
 - Travelers
 - Residents of areas of United States with past transmission of chikungunya virus
- Disease burden from acute disease and sequelae
- Additional vaccine data in younger age groups and/or additional chikungunya vaccines

Acknowledgements

- Chikungunya Vaccines Work Group members
- Nicole Lindsey
- Erin Staples