

Update on chikungunya and chikungunya vaccines

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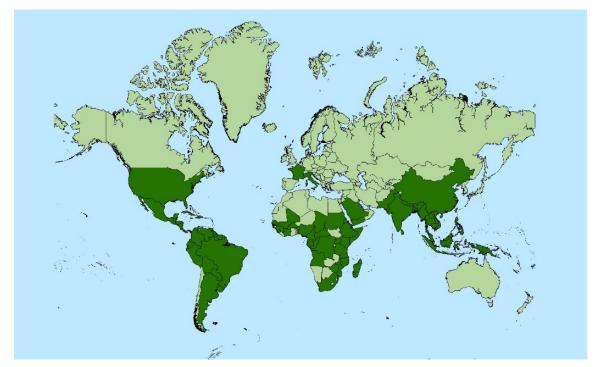
Chikungunya

- Mosquito-borne disease
- Key vectors are Aedes aegypti and Aedes albopictus mosquitoes



Distribution and virus transmission

- Typically tropical and subtropical regions
- Periodically causes large outbreaks, often with high attack rates



Countries and territories with current or past transmission of chikungunya virus

Key features of acute chikungunya virus disease

- Febrile illness with typically severe arthralgia, can be debilitating
- Other symptoms include headache, rash, myalgia, anorexia
- No anti-viral treatment available and management is supportive





Image above from : https://www.paho.org/en/topics/chikungunya

Complications of chikungunya

- Rare serious complications (e.g., myocarditis, hepatitis, neurologic illness)
- Deaths rare and reported mostly in
 - Older adults, particularly those with comorbidities
 - Young infants infected perinatally or by mosquito bites



Image from: https://www.paho.org/en/topics/chikungunya



Bin S et al, Clin Case Rep 2023

Chronic arthralgia following chikungunya

- Acute symptoms usually resolve in 7–10 days
- Some patients have continuation or relapse of symptoms
- Ongoing arthralgia of variable severity might be present in up to ~50% at 3 months and ~30% at 12 months¹



Chikungunya among U.S. travelers

- Approximately 100–200 reported cases annually
- Infection most commonly acquired in locations in Asia and Americas
- Greatest risk factor for travelers is traveling to area with outbreak



Chikungunya vaccines

Live attenuated chikungunya vaccine



- Manufactured by Valneva as IXCHIQ
- Licensed November 9, 2023
- Age group currently adults ≥18 years
- Single dose schedule

Recommendations for travelers approved February 2024

- ACIP recommends the live attenuated chikungunya vaccine for persons aged ≥18 years traveling to a country or territory where there is a chikungunya outbreak
- In addition, the vaccine **may be considered** for the following persons traveling to a country or territory without an outbreak but with evidence of chikungunya virus transmission among humans within the last 5 years
 - Persons aged >65 years, particularly those with underlying medical conditions,
 who are likely to have at least moderate exposure* to mosquitoes, OR
 - Persons staying for a cumulative period of 6 months or more

^{*}Moderate exposure could include travelers who might have at least 2 weeks (cumulative) of exposure to mosquitoes in indoor or outdoor settings

Recommendations for use among laboratory workers approved February 2024

 ACIP recommends live attenuated chikungunya vaccine for laboratory workers with potential for exposure to chikungunya virus

Updates on live attenuated chikungunya vaccine

- Adolescents aged 12–17 years: expected submission to FDA in 2024
- Children aged 1–11 years: clinical trial began December 2023
- Long term persistence trial ongoing
 - High seroresponse rate (97%) at 2 years
 - Monitoring continuing through 10 years to determine if booster dose needed in future

Virus-like particle chikungunya vaccine

- Manufactured by Bavarian Nordic
- Licensure possible February 2025
- Intended age group is adolescents and adults aged ≥12 years
- Single dose schedule

Licensure through accelerated approval pathway

- Traditional approval challenging and clinical development would likely have been delayed
 - Efficacy trial with disease endpoint difficult as outbreaks unpredictable and duration can be relatively short
 - No established immunologic correlate of protection
- Accelerated approval pathway endorsed at FDA VRBAC* meeting, 2019
 - FDA can grant for products for serious conditions that fill unmet medical need
 - Effectiveness demonstrated by controlled trials showing vaccine has effect on surrogate endpoint reasonably likely to predict clinical benefit
 - Marker of protection for virus-like particle vaccine based on neutralizing antibody titer estimated from validated non-human primate model
 - Post-licensure requirement for controlled trials to confirm clinical benefit

ACIP recommendations for use of chikungunya vaccines

| Population | Live attenuated vaccine | Virus-like particle vaccine |
|--|-------------------------|-----------------------------|
| Travelers | Completed* | <i>Pending</i> [†] |
| Laboratory workers | Completed | Pending |
| Residents of U.S. territories with transmission risk | Pending | Pending |
| Residents of U.S. states with transmission risk | Pending | Pending |

^{*}Adults aged ≥18 years

