Update on Dengue Vaccines

Joshua Wong, MD
Medical Officer | NCEZID/DVBD/Dengue Branch

Meeting of the Advisory Committee on Immunization Practices

June 26, 2024

Dengue Epidemiology Globally

Countries reporting locally acquired dengue cases,
March 2023–April 2024

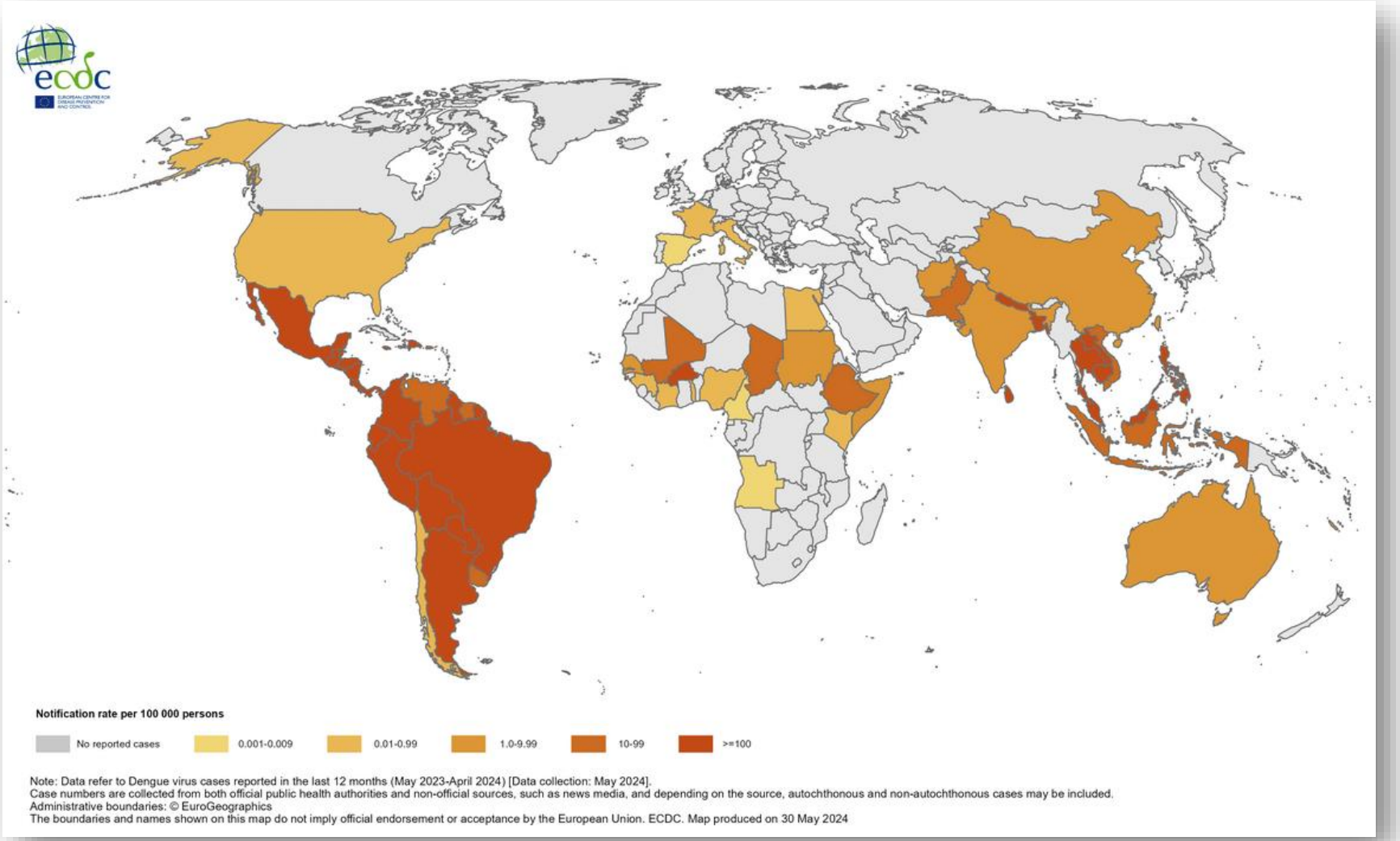
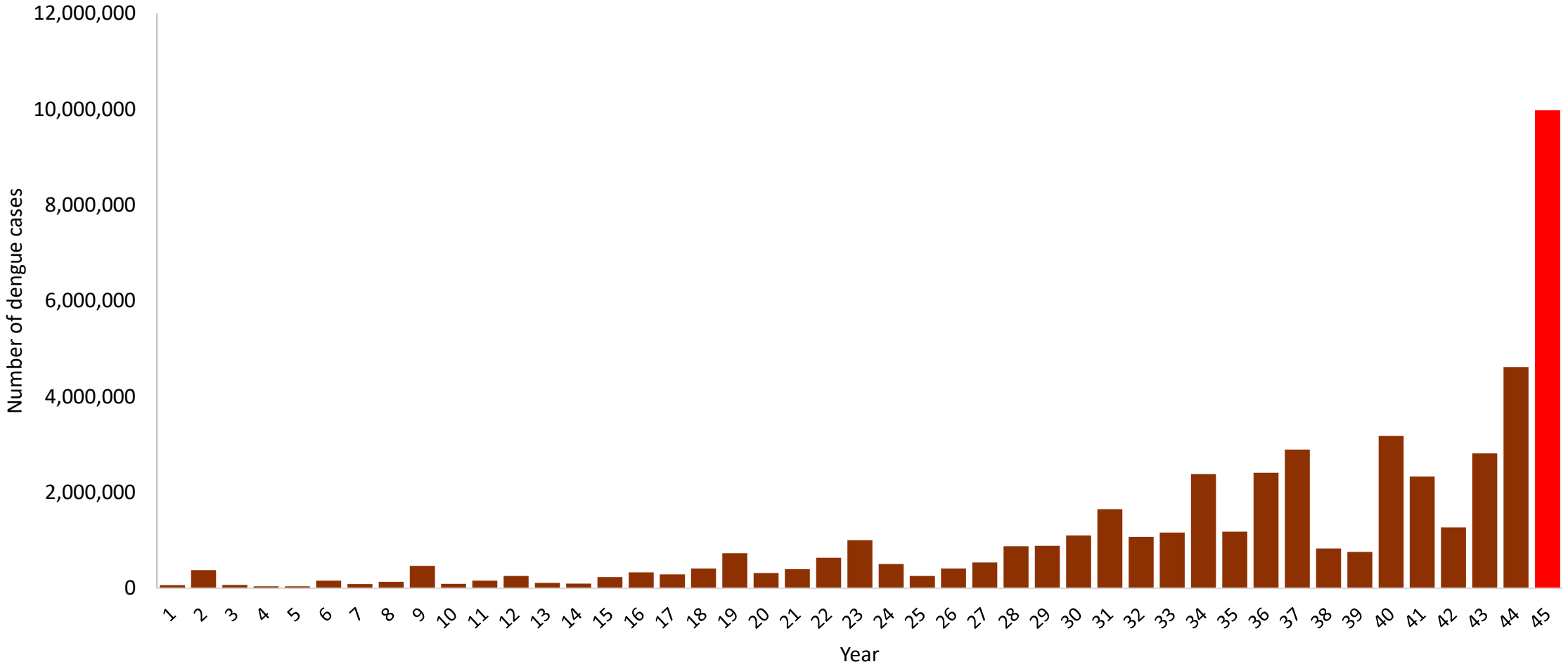


Image from: https://www.ecdc.europa.eu/en/publications-data/countriesterritories-reporting-dengue-cases-march-2023-and-april-2024. Accessed 6/1/2024

Dengue cases in the Americas, 1980–2024

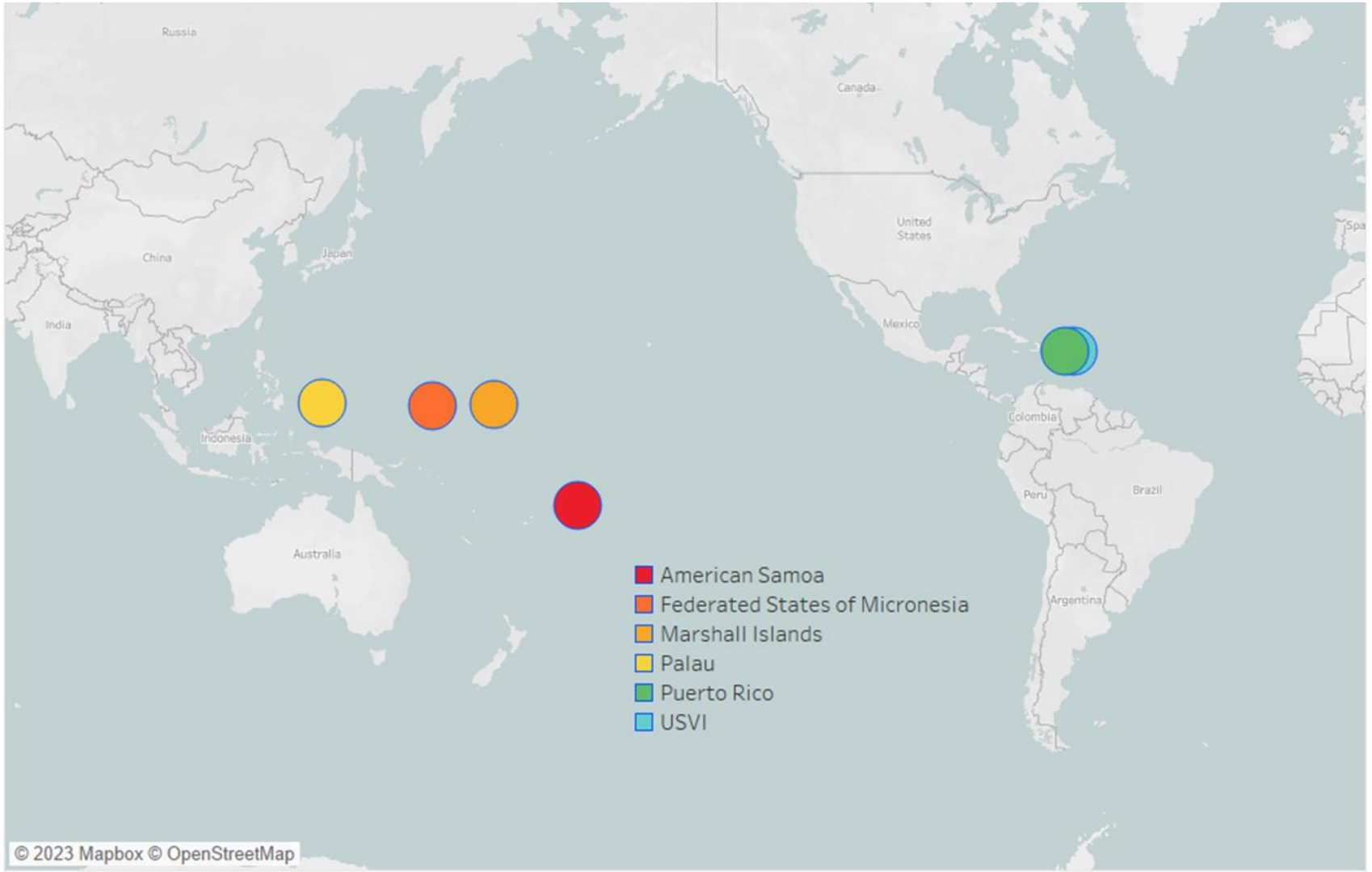
Nearly 10 million cases reported in 2024 as of June 25.



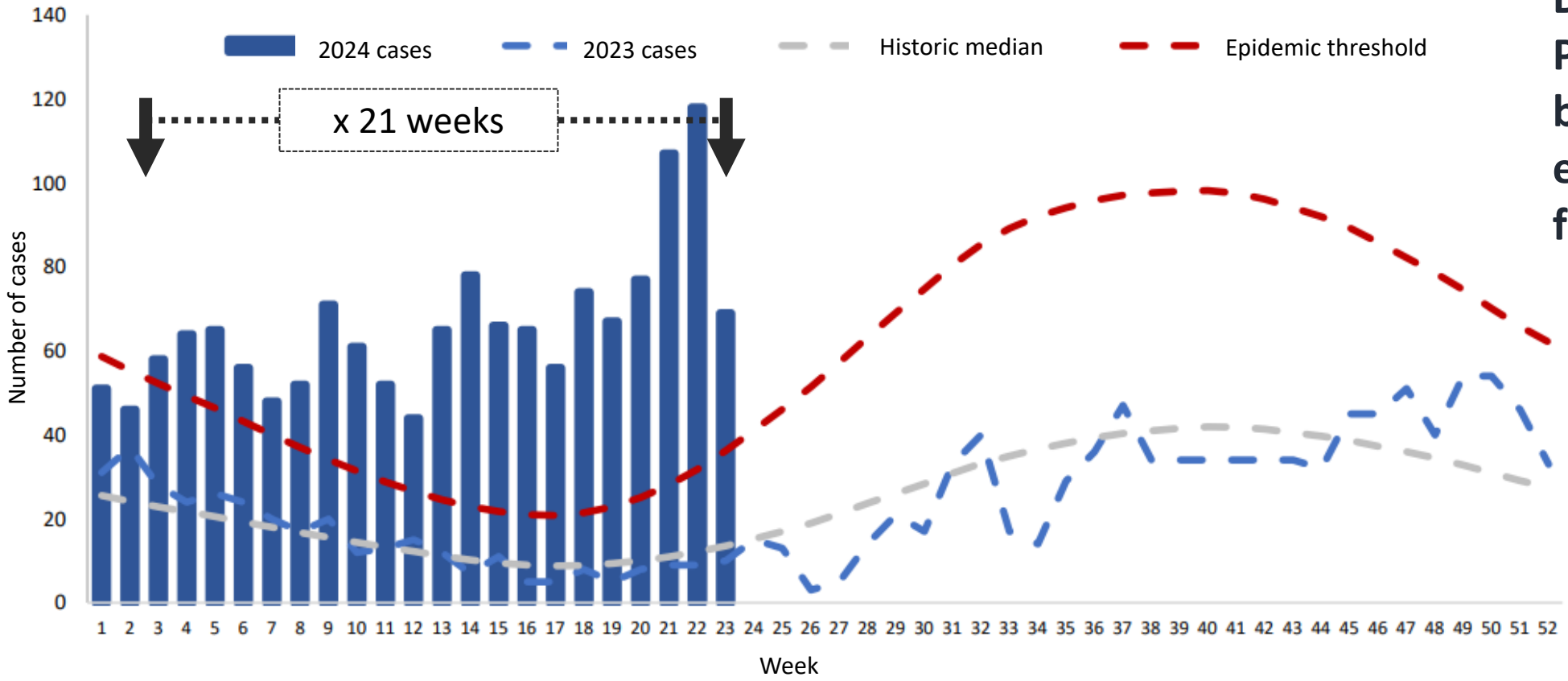
Data from PAHO PLISA Health Information Platform for the Americas. https://www3.paho.org/data/index.php/es/temas/indicadores-dengue.html. Accessed 6/25/2024

Dengue Epidemiology in the U.S.

In the United States, dengue is endemic in **6 U.S. territories and freely associated states.**



Puerto Rico declared a public health emergency due to a dengue epidemic in March 2024.



DENV infections in Puerto Rico have been above the epidemic threshold for 21 weeks.

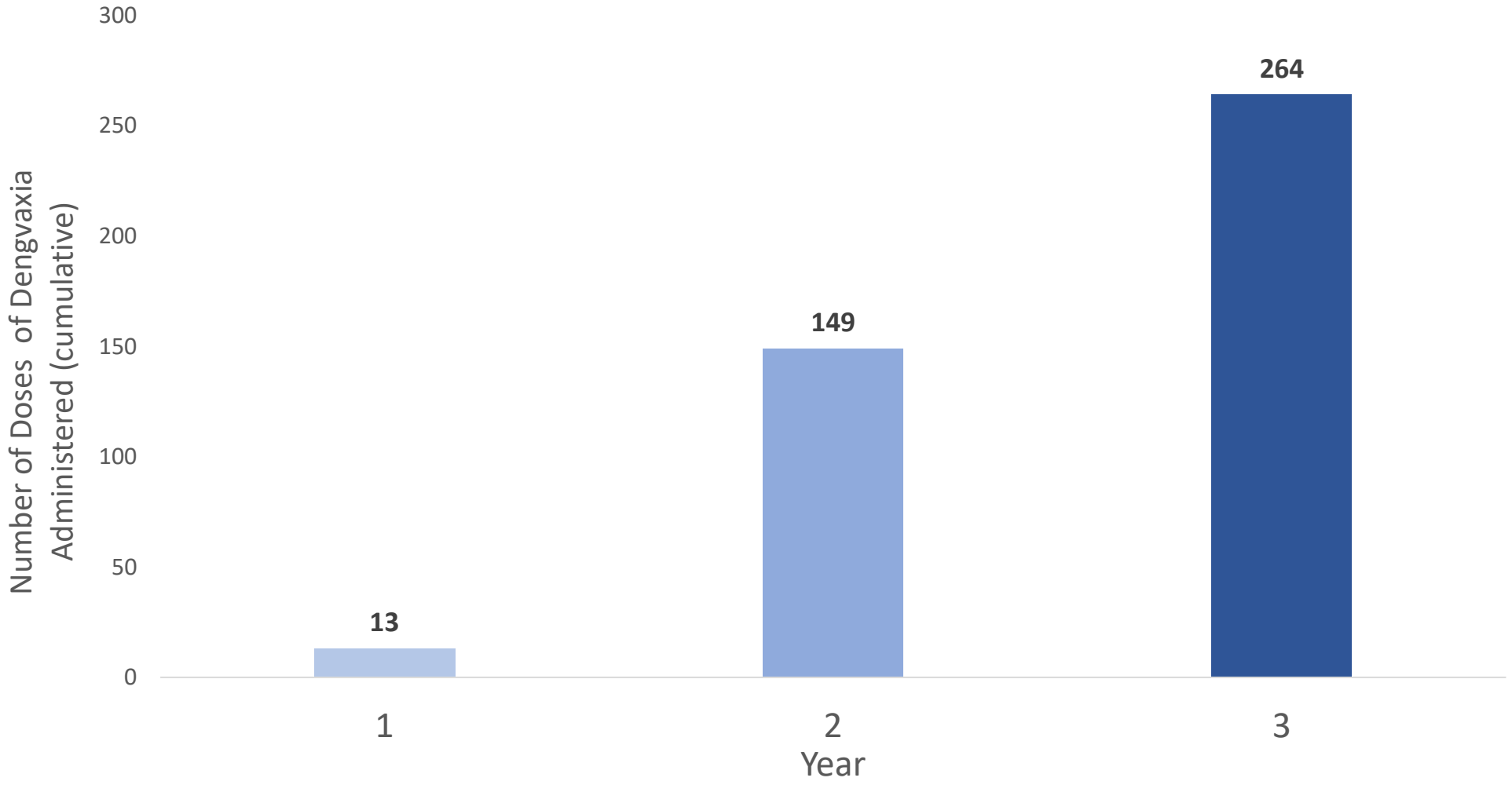
Weekly Arboviral Report – Week 23, Puerto Rico Department of Health, accessed 6/25/2024. https://www.salud.pr.gov/CMS/DOWNLOAD/9050

Update on Dengvaxia in Puerto Rico

The first dengue vaccine in Puerto Rico was administered on September 7, 2022.

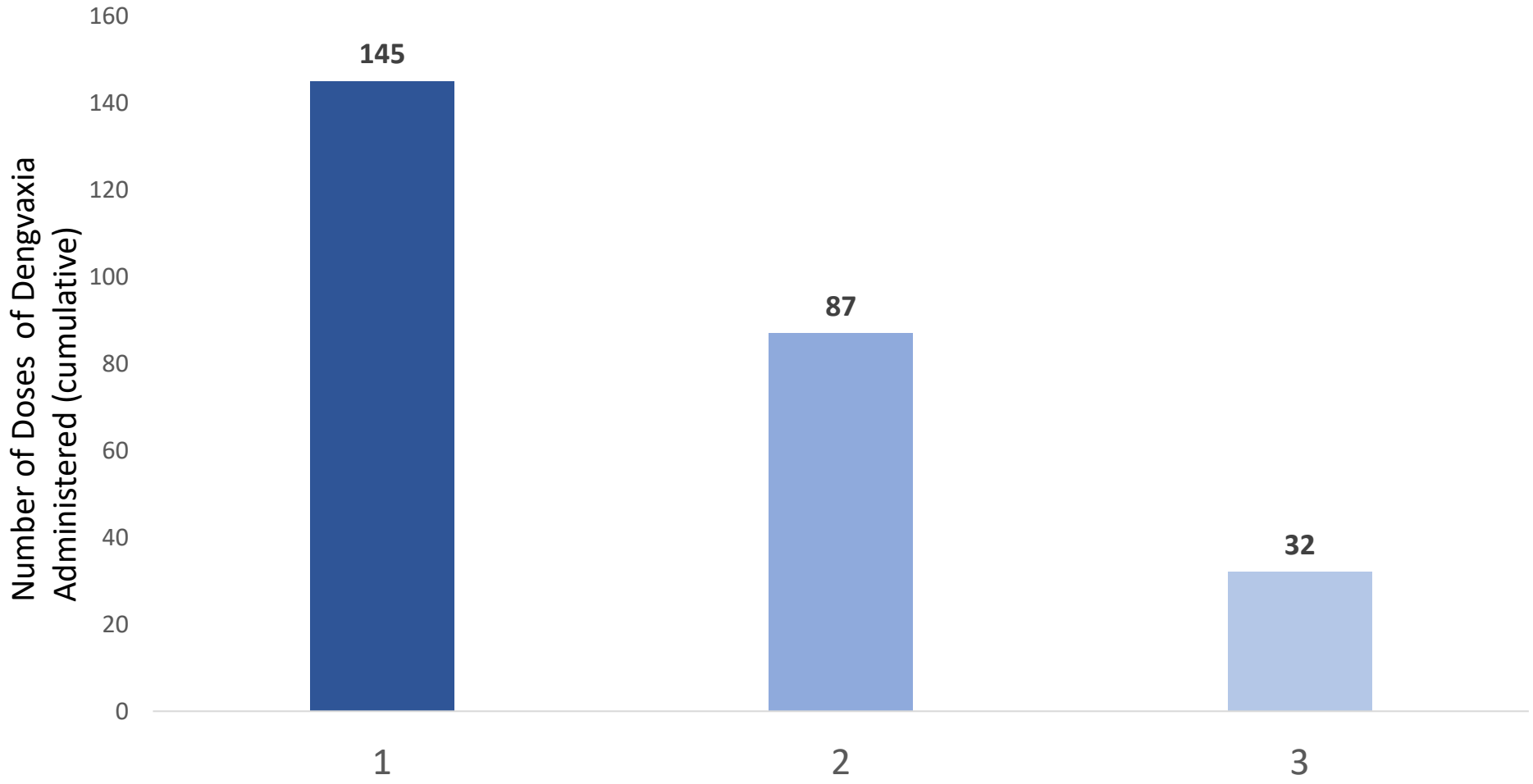
Images from: https://www.elvocero.com/actualidad/salud/administran-la-primera-vacuna-contra-el-dengue/article_9c49436a-2e4f-11ed-beba-0bf2bccaeb1f.html Accessed 6/12/2024.

Since Dengvaxia vaccination began in Puerto Rico, 264 doses have been administered.*



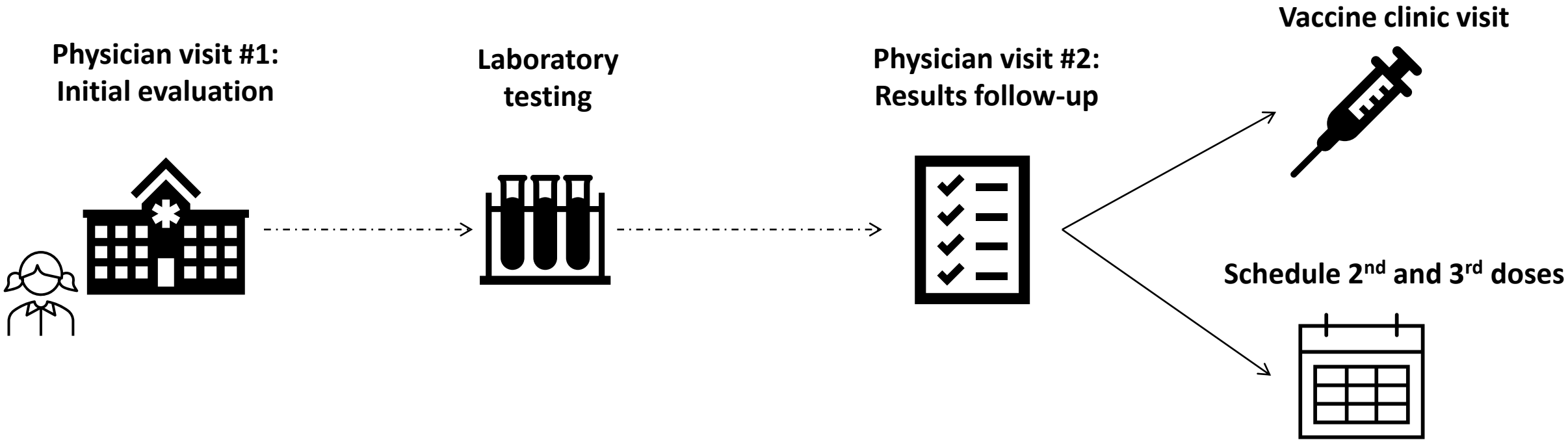
Data used with permission from the Puerto Rico Department of Health, Vaccine Program. Current as of June 24, 2024.

Since Dengvaxia vaccination began in Puerto Rico, 145 individuals have started the series.



Data used with permission from the Puerto Rico Department of Health, Vaccine Program. Current as of June 24, 2024.

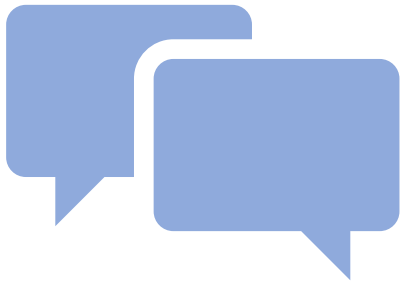
Multiple visits to healthcare providers to determine eligibility and start vaccination has complicated implementation.



Major barriers to uptake have included:

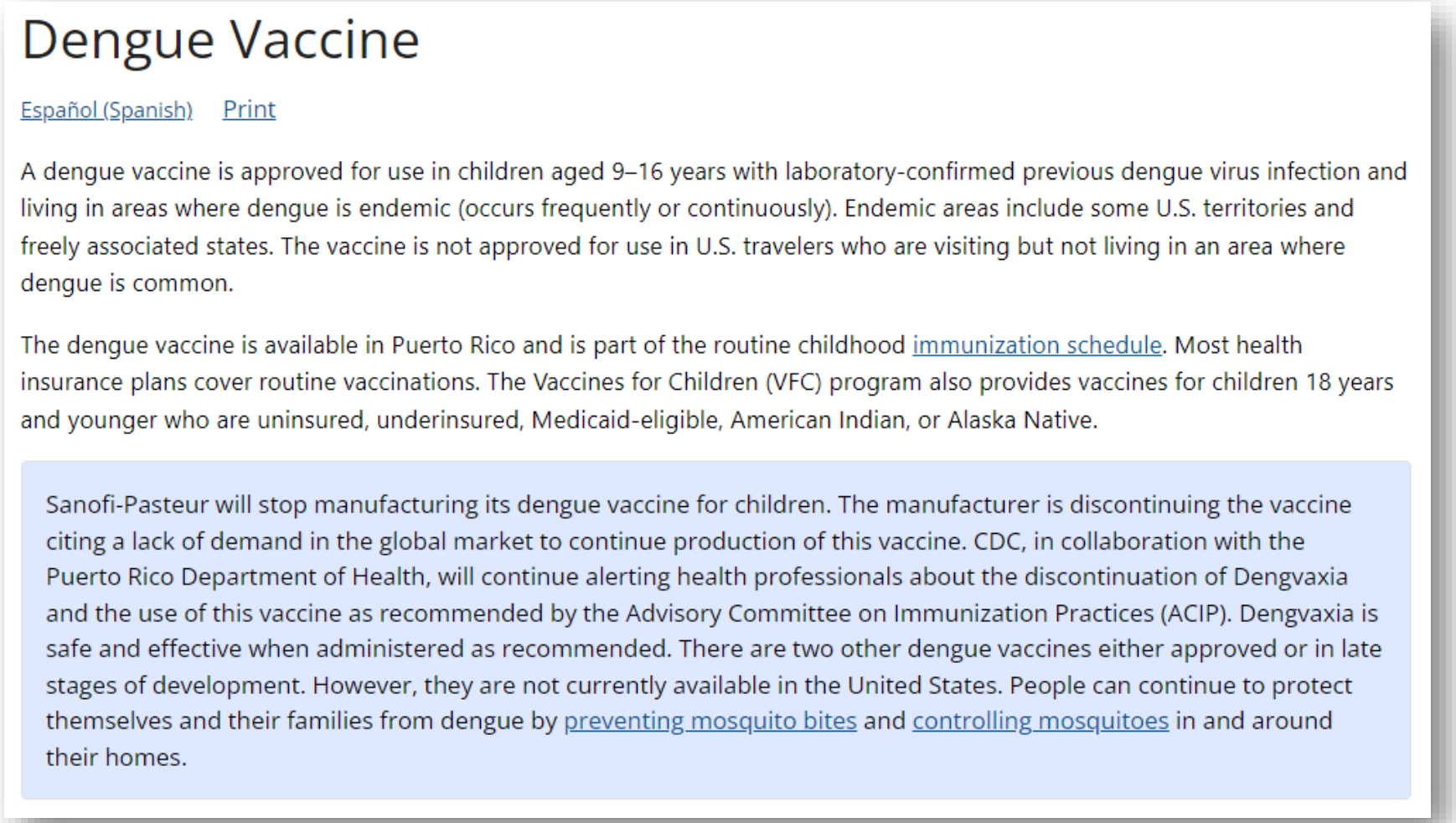
Prevaccination Testing

Complex billing processes



Limited vaccine messaging

CDC has updated its website with information on discontinuation of Dengvaxia.



Dengue Vaccine

Español (Spanish) Print

A dengue vaccine is approved for use in children aged 9–16 years with laboratory-confirmed previous dengue virus infection and living in areas where dengue is endemic (occurs frequently or continuously). Endemic areas include some U.S. territories and freely associated states. The vaccine is not approved for use in U.S. travelers who are visiting but not living in an area where dengue is common.

The dengue vaccine is available in Puerto Rico and is part of the routine childhood immunization schedule. Most health insurance plans cover routine vaccinations. The Vaccines for Children (VFC) program also provides vaccines for children 18 years and younger who are uninsured, underinsured, Medicaid-eligible, American Indian, or Alaska Native.

Sanofi-Pasteur will stop manufacturing its dengue vaccine for children. The manufacturer is discontinuing the vaccine citing a lack of demand in the global market to continue production of this vaccine. CDC, in collaboration with the Puerto Rico Department of Health, will continue alerting health professionals about the discontinuation of Dengvaxia and the use of this vaccine as recommended by the Advisory Committee on Immunization Practices (ACIP). Dengvaxia is safe and effective when administered as recommended. There are two other dengue vaccines either approved or in late stages of development. However, they are not currently available in the United States. People can continue to protect themselves and their families from dengue by preventing mosquito bites and controlling mosquitoes in and around their homes.

Dengue Vaccine | Dengue | CDC

Update on Other Dengue Vaccines in the U.S.

Takeda voluntarily withdrew TAK-003 (Qdenga) from FDA review in July 2023.

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Takeda Announces Voluntary Withdrawal of U.S. Biologics License Application (BLA) for Dengue Vaccine Candidate TAK-003

July 11, 2023

Share

OSAKA, Japan and CAMBRIDGE, Massachusetts, July 11, 2023 – Takeda (TSE:4502/NYSE:TAK) today announced that the Company has voluntarily withdrawn the U.S. Biologics License Application (BLA) for its dengue vaccine candidate, TAK-003, following discussions with the U.S. Food and Drug Administration (FDA) on aspects of data collection, which cannot be addressed within the current BLA review cycle. The future plan for TAK-003 in the U.S. will be further evaluated given the need for travelers and those living in dengue-endemic areas of the U.S., such as Puerto Rico. The vaccine is approved in multiple endemic and non-endemic countries, with more approvals expected over the coming years.

Takeda/Newsroom

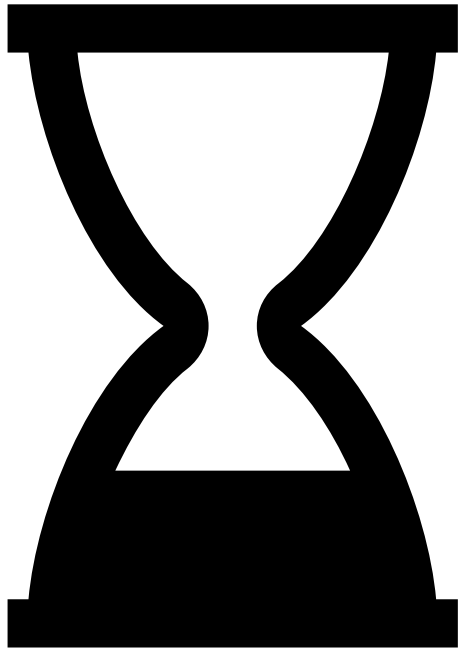
The TV003/TV005 dengue vaccine is in late-stage phase 3 trials.

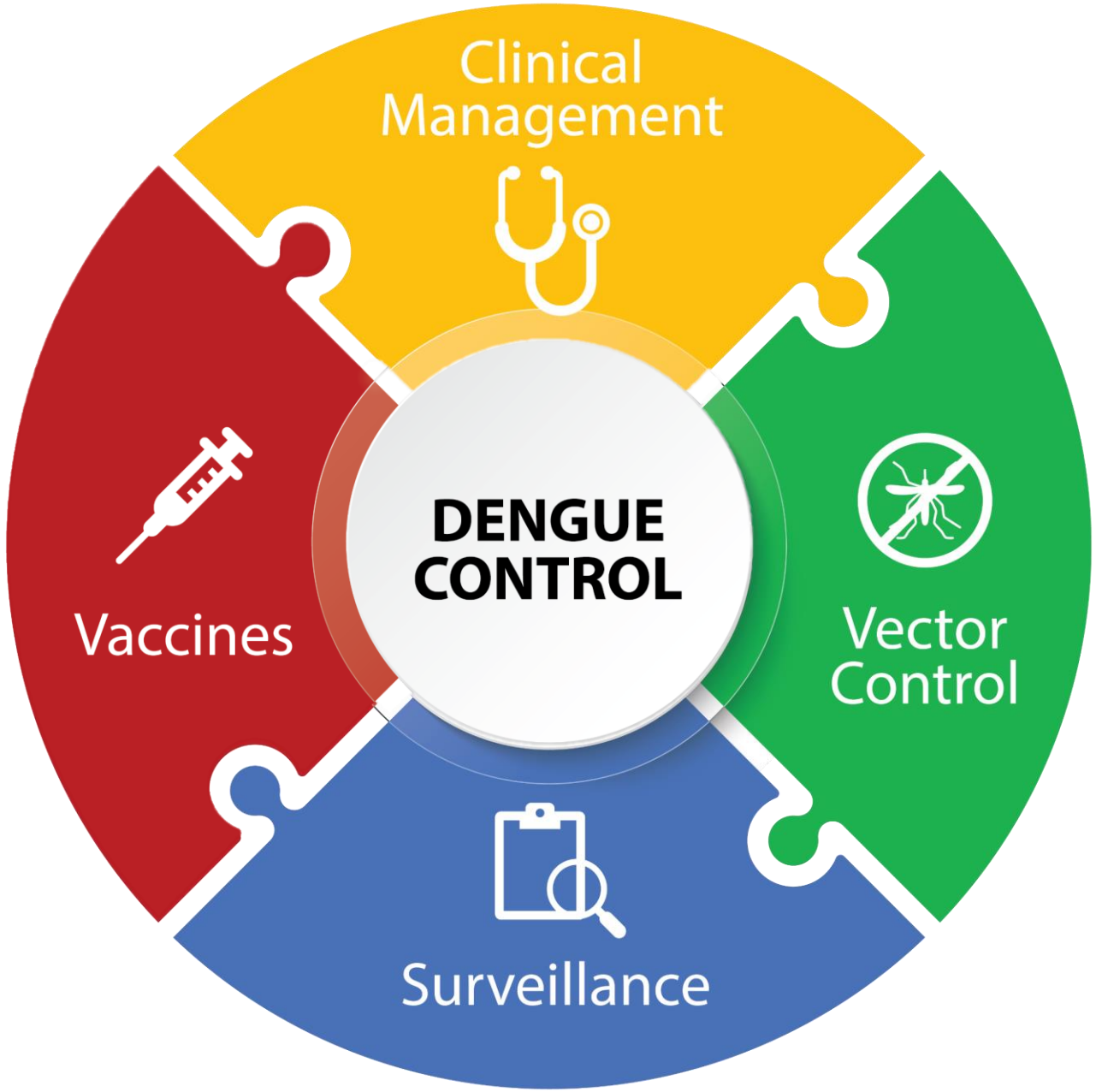
- **Developed by the US National Institutes of Health (NIH).**
- **Licensed to Merck in the U.S. and the Instituto Butantan in Brazil.**
- **Phase 3 trials in Brazil are ongoing.**
  - High efficacy and safety results during the first two year follow-up period have been published.*
  - DENV-3 or DENV-4 not observed during this period, limiting evaluation of VE against these serotypes.
  - Five year follow-up data expected later this year.

*Kallás, E. G., et al. (2024). "Live, Attenuated, Tetravalent Butantan-Dengue Vaccine in Children and Adults." N Engl J Med 390(5): 397-408.
Image from: https://revistapesquisa.fapesp.br/en/butantans-dengue-vaccine-is-80-effective/ accessed 6/11/2024.

No dengue vaccines will be available in the U.S. after the discontinuation of Dengvaxia.

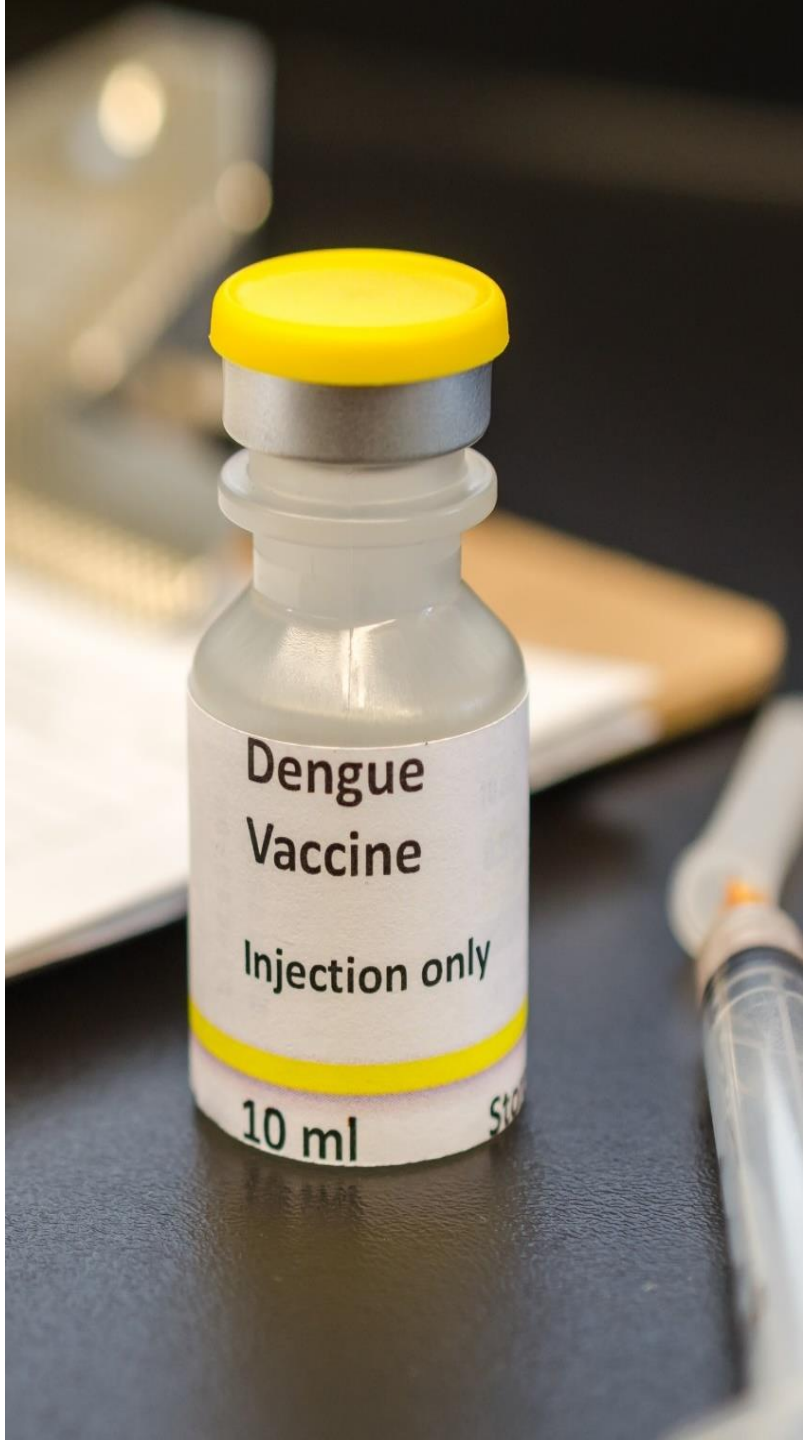
- No dengue vaccines are currently under review by FDA.
- The ACIP Dengue Vaccines Workgroup group will be paused until new dengue vaccines are submitted to FDA for approval.




Clinical Management
Vaccines
DENGUE CONTROL
Vector Control
Surveillance

Conclusion

- Dengue cases globally are increasing.
- Puerto Rico has declared a public health emergency due to the dengue epidemic.
- There will be no other vaccines available in the U.S. after Dengvaxia manufacturing is discontinued.
- The Dengue Vaccines Workgroup will be paused until new vaccines are submitted for FDA review.
- Vaccines are just one part of a multilayered approach to reducing morbidity by dengue.



Questions?

ACIP Dengue Vaccines Workgroup and Support Team

ACIP Members
Wilbur Chen (Chair)
Kathy Poehling
Beth Bell
Veronica McNally

CDC Co-Leads
Gabriela Paz-Bailey
Laura Adams

Ex Officio Members
Kaitlyn Morabito (NIH)
Ralph LeBlanc (FDA)
Ihid Carneiro Leao (FDA)
Kirk Prutzman (FDA)
Srihari Seshadri (DOD)

Liaison Representatives
Elizabeth Barnett (AAP)
Rob Schechter (AIM)

Consultants
Edwin Asturias
Robert Atmar
Alan Barrett
Iris Cardona
Anna Durbin
Tony Marfin
Kristen Pierce
Anita Shet

CDC Contributors
Joshua Wong
Nicole Medina
Mimi Eckert
Rachel Eidex
Alfonso Hernandez
Susan Hills
Terri Hyde
Mike McNeil
Jorge Munoz

Erin Staples
Cindy Weinbaum
Rita Helfand

Non-Members
Mitchelle Flores-Febo
Parker Acevedo
Diana Duran
Angel Rivera

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov