Maine CDC Clinician Update: Mpox

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DRAFT

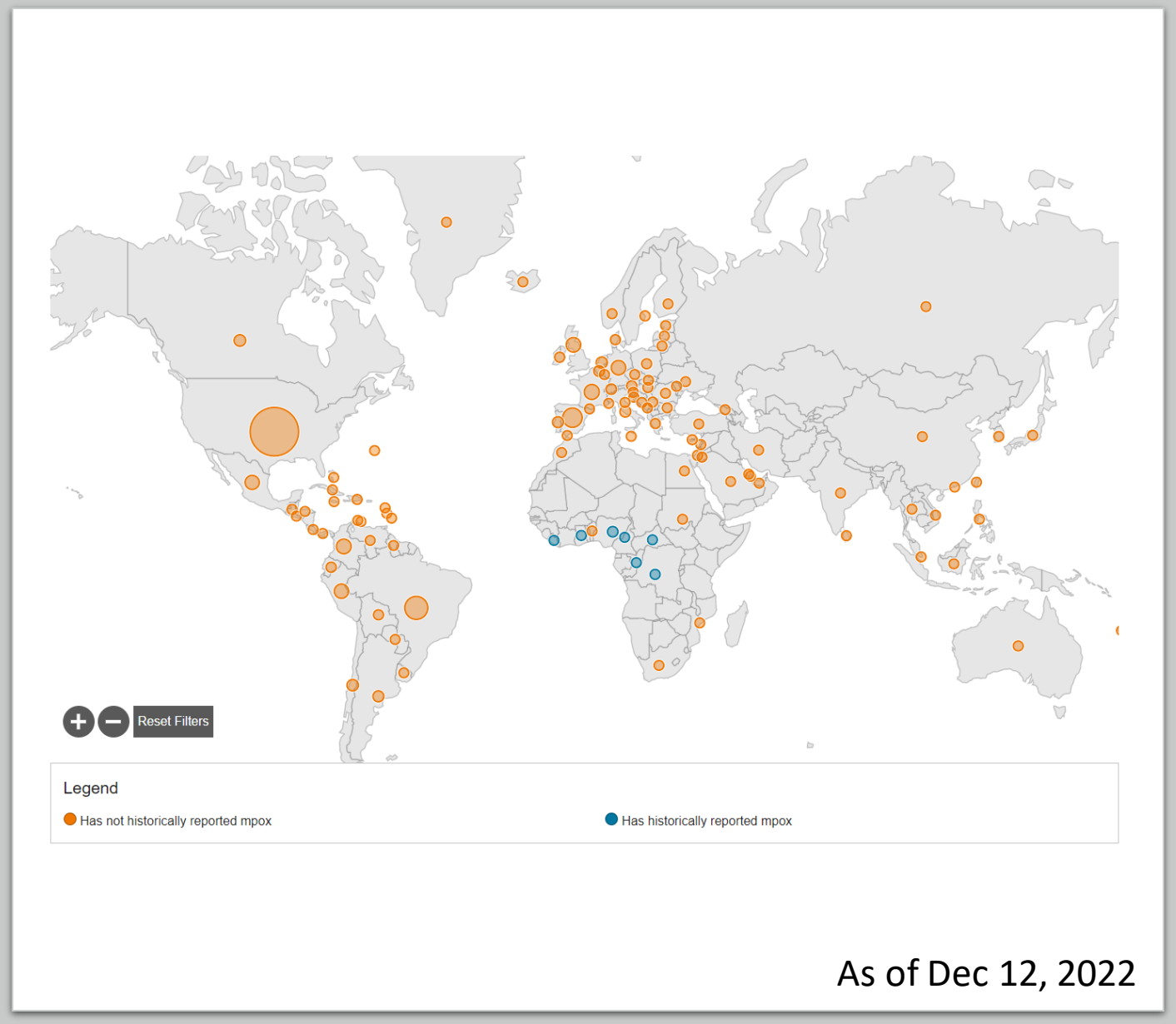
December 13, 2022

STATE OF MAINE
Department of
Health and Human Services

Epi Updates

Globally:

- >82k cases
  - in 110 locations, including 103 that haven't historically reported mpox
- 65 deaths
- Highest incidence:
  - U.S.
  - Brazil
  - Spain
  - France
  - Colombia
  - United Kingdom
  - Germany

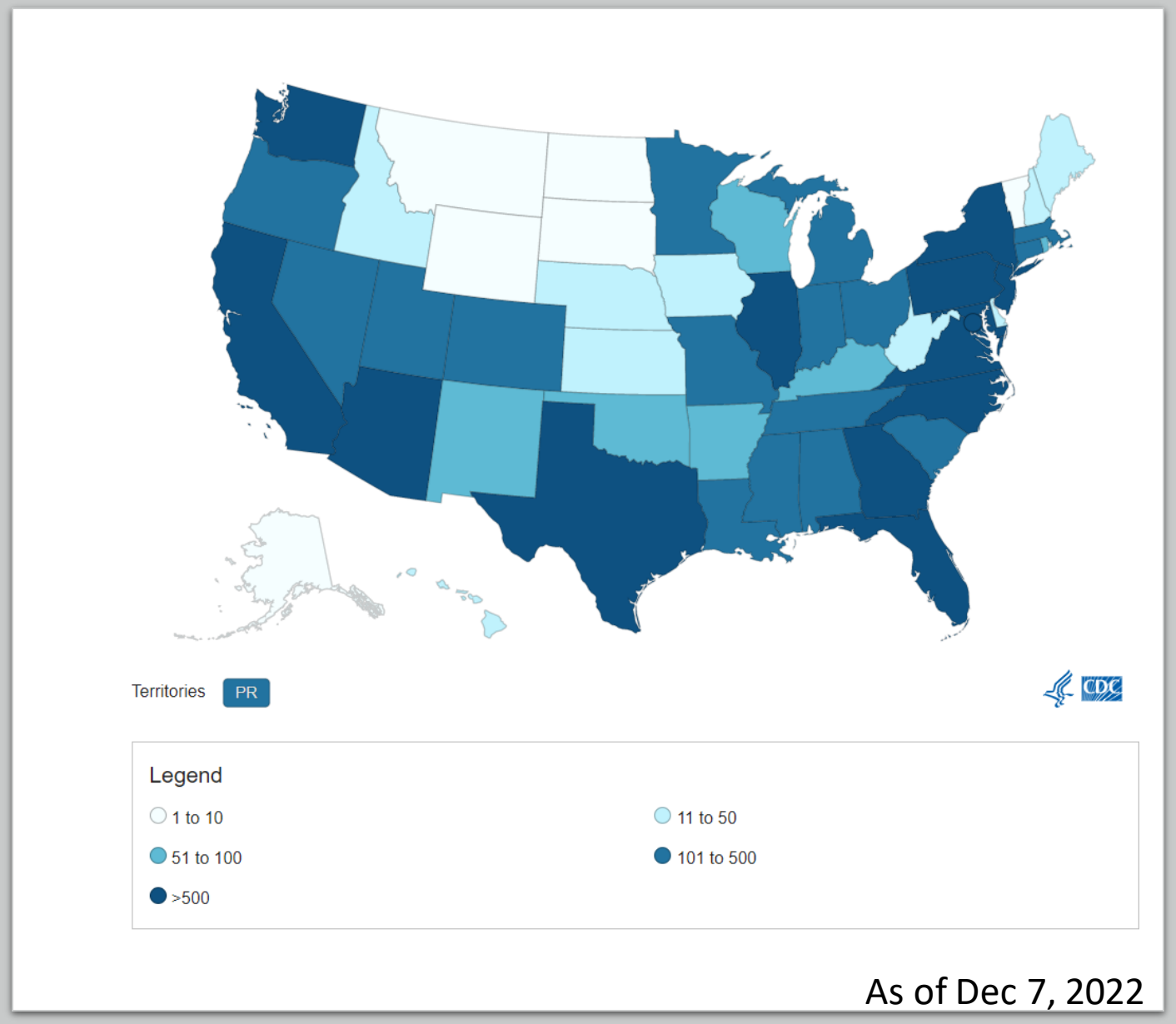


As of Dec 12, 2022

https://www.cdc.gov/poxvirus/monkeypox/response/2022/world-map.html

Domestically:

- >29K cases
- 20 deaths
- Highest incidence:
  - California
  - New York
  - Texas
  - Florida
  - Georgia
  - Illinois



https://www.cdc.gov/poxvirus/monkeypox/response/2022/us-map.html

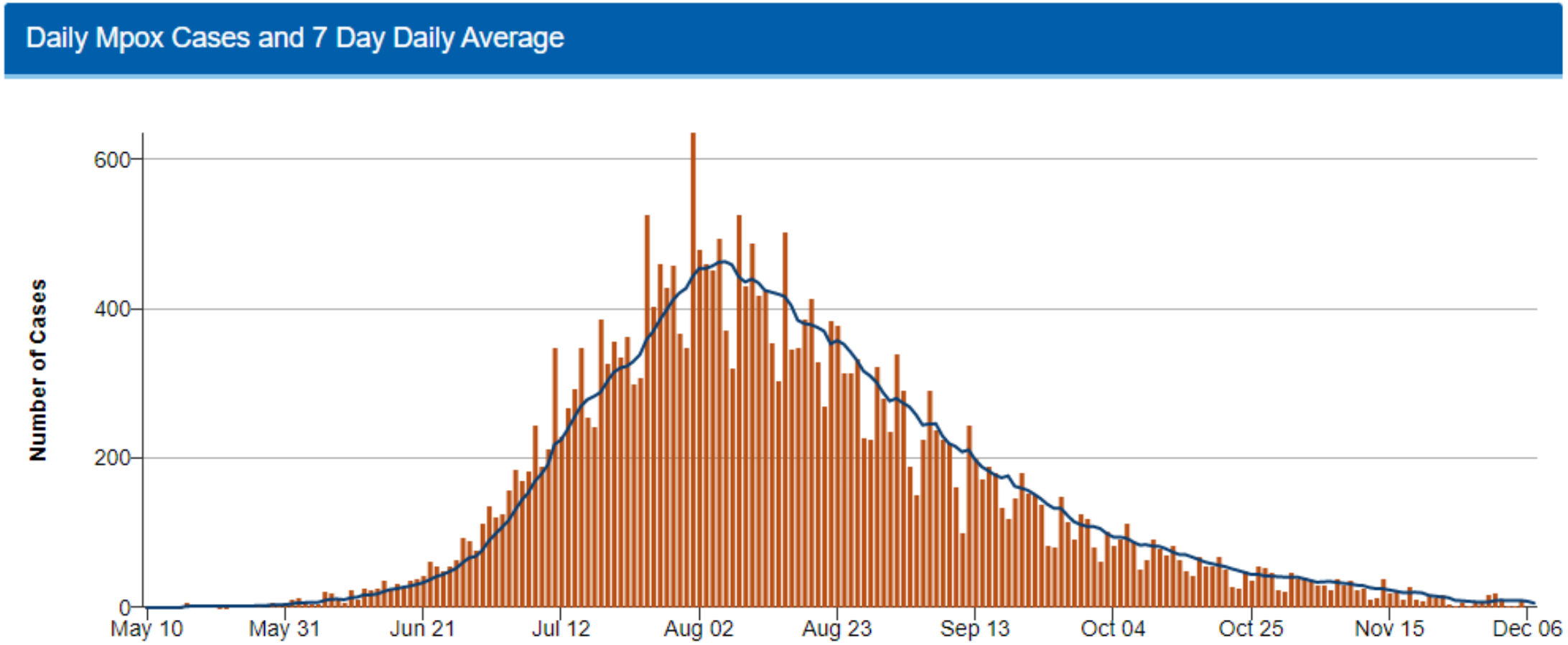
Mpox Cases in Maine

Confirmed and Probable Mpox Cases in Maine (Updated 12/7/2022)	
County	**Number of Confirmed and Probable Cases***
Androscoggin	2
Aroostook	2
Cumberland	3
Hancock	1
Knox	1
Sagadahoc	1
York	3
Total	**13**

*Cases may be reassigned to other states upon investigation.

https://www.maine.gov/dhhs/mecdc/infectious-disease/epi/zoonotic/monkeypox.shtml

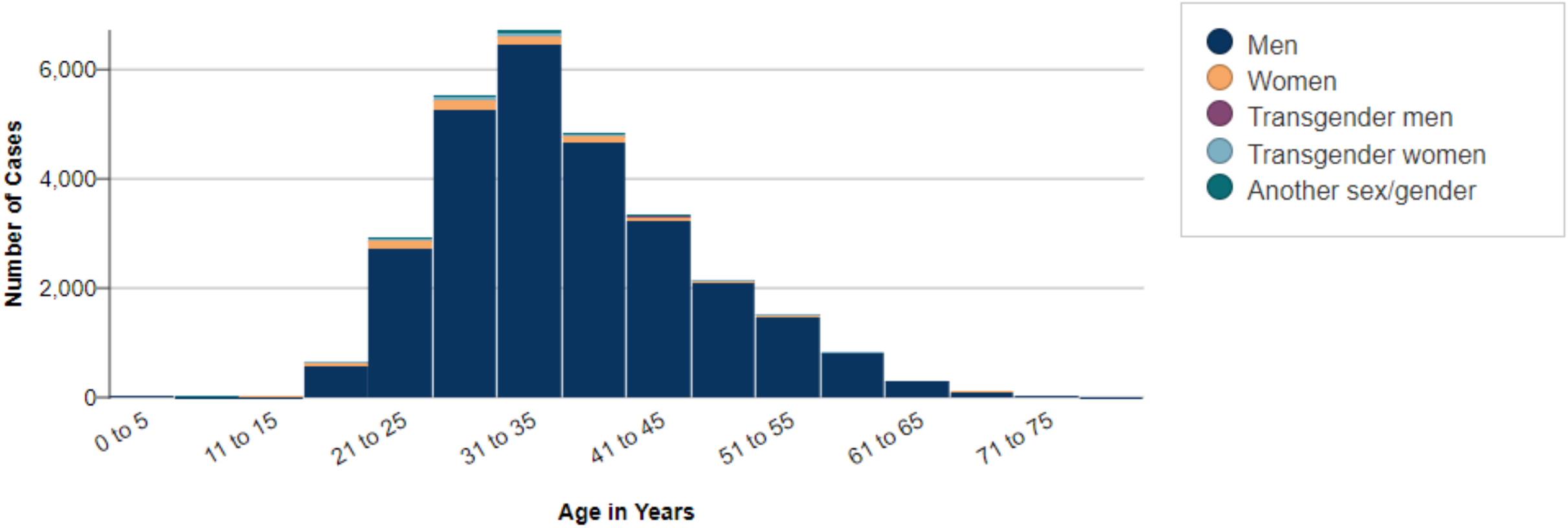
U.S. Mpox Case Trends



As of Dec 7, 2022

https://www.cdc.gov/poxvirus/monkeypox/response/2022/mpox-trends.html

U.S. Mpox Cases by Age and Gender

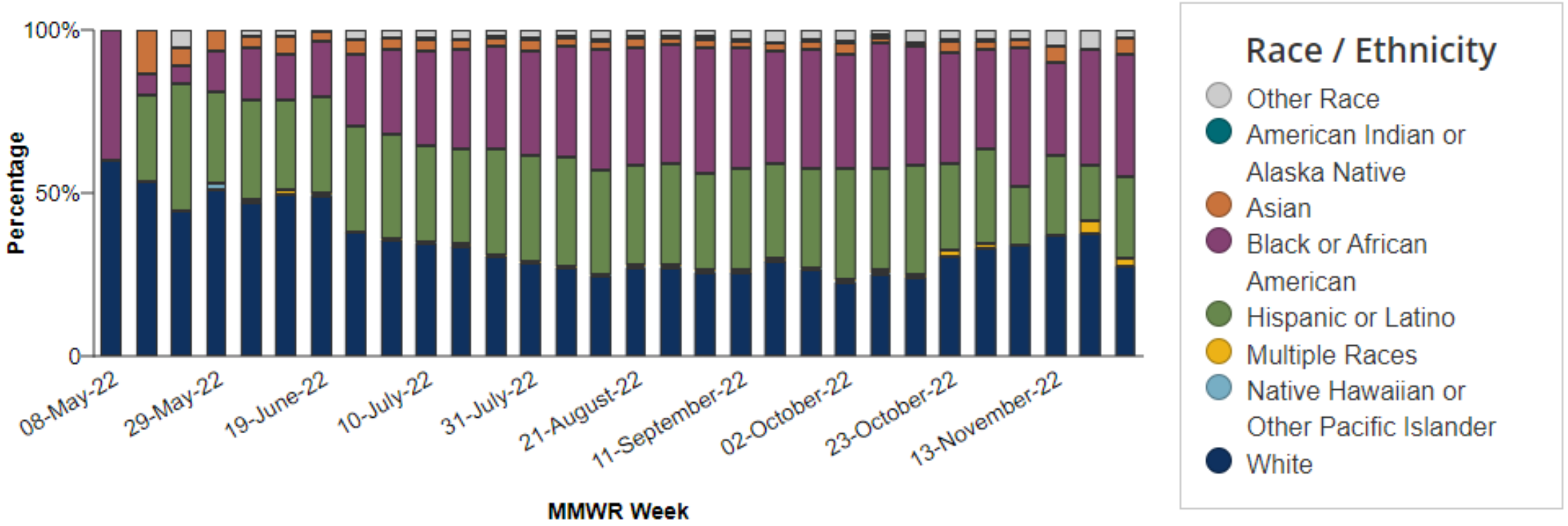


As of Dec 7, 2022

https://www.cdc.gov/poxvirus/monkeypox/response/2022/demographics.html

U.S. Mpox Cases by Race/Ethnicity:

A disproportionate number of cases are among Black or Hispanic persons



As of Dec 7, 2022

https://www.cdc.gov/poxvirus/monkeypox/response/2022/demographics.html

U.S. Mpox Cases: Signs and Symptoms

Most common:

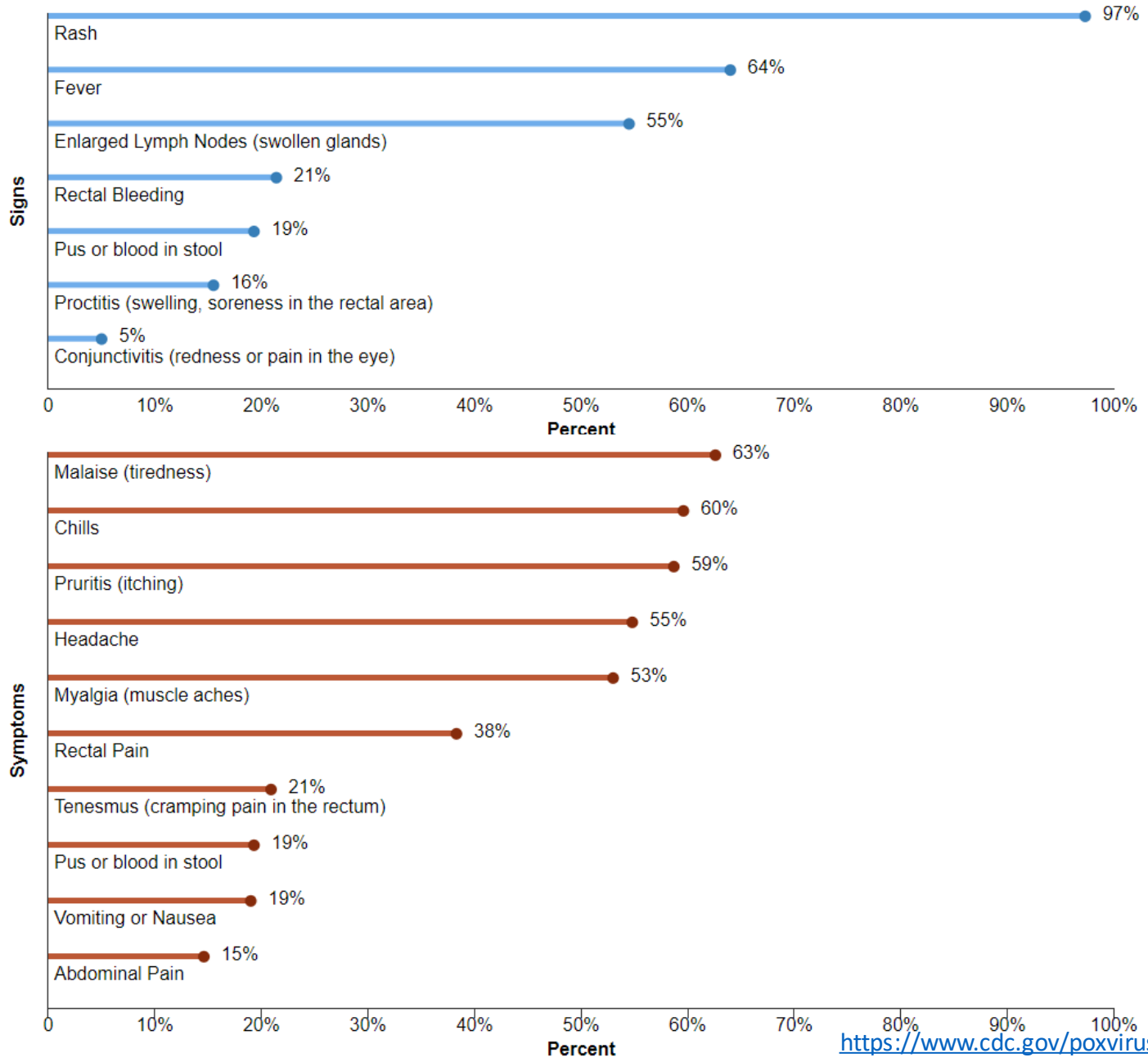
Rash (97%)

Fever (64%)

Malaise (63%)

Chills (60%)

Pruritis (59%)



As of Nov 30, 2022

https://www.cdc.gov/poxvirus/monkeypox/response/2022/demographics.html

Treatment Updates

As a reminder: TPOXX

- Because prognosis depends on multiple factors (i.e., initial health status, concurrent illnesses, previous vaccination history, and comorbidities), supportive care and pain control may not be enough for some patients, in which case TPOXX should be considered
- Is an FDA approved antiviral medication for the treatment of smallpox in adults and children
- Data are not available on the effectiveness of TPOXX in treating mpox infections in people
- A clinical trial focused on safety in healthy people without mpox virus showed the drug had an acceptable safety profile
- Available as a pill or an injection for IV administration

TPOXX

How to access TPOXX:

- **Preferred method is through the Study of Tecovirimat for Human Monkeypox Virus (STOMP)**
- Alternatively, U.S. CDC holds an Expanded Access Investigational New Drug Protocol (EA-IND) for TPOXX that allows for the use of stockpiled TPOXX to treat mpox.
  - Treatment can begin **after** obtaining informed consent.
    - Forms requested under the EA-IND can all be returned to U.S. CDC **after** treatment begins.
    - Required forms:
      - https://www.maine.gov/dhhs/mecdc/infectious-disease/epi/zoonotic/mpox-providers.shtml#treatment

Call Center: 1-855-876-9997 (U.S. only)

STOMP
Study of Tecovirimat for Human Monkeypox Virus

STOMP About the Study Participating Research Sites

Study of Tecovirimat for Human Monkeypox Virus (STOMP)

Other Treatment Updates

Brincidofovir (Temblexa)

- Now available, in oral and tablet formulations
- Antiviral, FDA approved for the treatment of human smallpox disease in adult and pediatrics
- No effectiveness data in human mpox
- Available from the strategic national stockpile for treatment of mpox to clinicians who request and obtain an FDA-authorized single-patient emergency use Investigational New Drug (EIND)

https://www.cdc.gov/poxvirus/monkeypox/clinicians/treatment.html

FDA's review criteria for Brincidofovir EIND requests

- Patients with positive test results for human mpox viral testing who:
  - Have severe disease OR are at high risk for progression to severe disease
  - AND meet either of the following:
    - Experience clinically significant disease progression while receiving tecovirimat or who develop recrudescence (initial improvement followed by worsening) of disease after an initial period of improvement on tecovirimat, *OR*
    - Are otherwise ineligible or have a contraindication for oral or intravenous tecovirimat

https://www.cdc.gov/poxvirus/monkeypox/clinicians/treatment.html#anchor_1655488353796

Brincidofovir

How to obtain:

- Submit an EIND request to FDA by email (DDI.EIND@fda.hhs.gov) or phone 301-796-3400 or 1-855-543-3784 during normal business hours (8 am-4:30 pm ET M-F). During after hours, call the FDA Emergency Coordinator at 1-866-300-4374 or 301-796-8240 or email CDER-EIND@fda.hhs.gov and call the CDER Emergency Coordinator at 301-796-9900.

Other Treatment Updates

Vaccinia Immune Globulin Intravenous (VIGIV)

- Licensed for the treatment of complications due to vaccinia vaccination
- Not approved for treatment of mpox
- CDC holds an expanded access IND protocol [PDF – 465 KB, 25 pages] that allows the use of stockpiled VIGIV for the treatment of orthopoxviruses (including mpox) in an outbreak
- Effectiveness data are not available
- Healthcare providers may consider its use in severe cases
- Available upon clinician request to US CDC on a case-by-case basis

Other Treatment Updates

Cidofovir (Vistide)

- An antiviral medication that is approved by the FDA [PDF – 6 pages] for the treatment of cytomegalovirus retinitis in patients with AIDS
- Available commercially as an injection
- Effectiveness data are not available
- Brincidofovir (a prodrug of cidofovir) may have an improved safety profile

In patients with severe symptoms

- Healthcare providers should consider consulting with:
  - Maine CDC (800-821-5821)
  - U.S. CDC (eocevent482@cdc.gov) or Emergency Operations Center (770) 488-7100)
- Clinicians seeking treatments for patients should work with Maine CDC and U.S. CDC to access appropriate treatments as soon as potential need becomes apparent.

Vaccination Updates

As a reminder: Jynneos

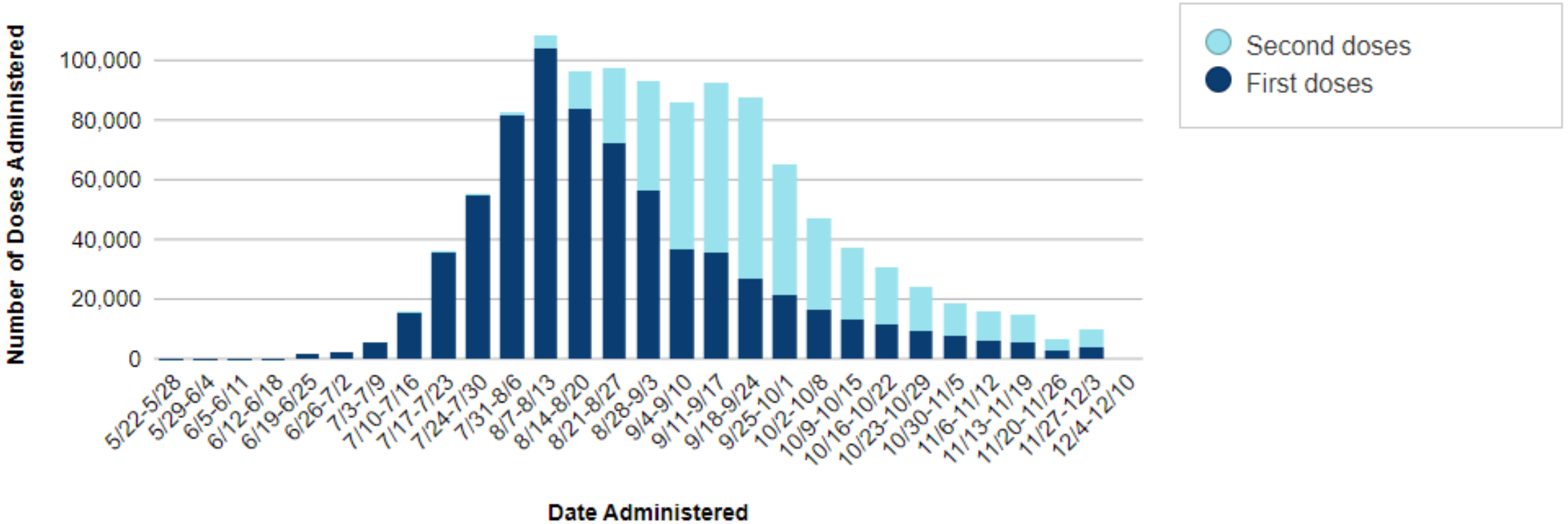
- Jynneos vaccine is approved for prevention of smallpox and mpox
- Preliminary vaccine effectiveness estimates against medically attended mpox disease in the U.S. are now available
- Vaccination, after exposure to a person with mpox, may help prevent the disease or make it less severe
  - U.S. CDC recommends initiating vaccination within 4 days following the date of exposure for the best chance to prevent onset of the disease
  - If initiated between 4-14 days following exposure, vaccination might be less effective
- Benefits might still outweigh risks when administering vaccine more than 14 days after exposure in some clinical situations (e.g., for a severely immunosupressed person with a recent sex partner confirmed to have mpox)
- Vaccination is not expected to provide benefit if it is given after onset of signs or symptoms of mpox begin

https://www.cdc.gov/poxvirus/mpox/interim-considerations/jynneos-vaccine.html#admin

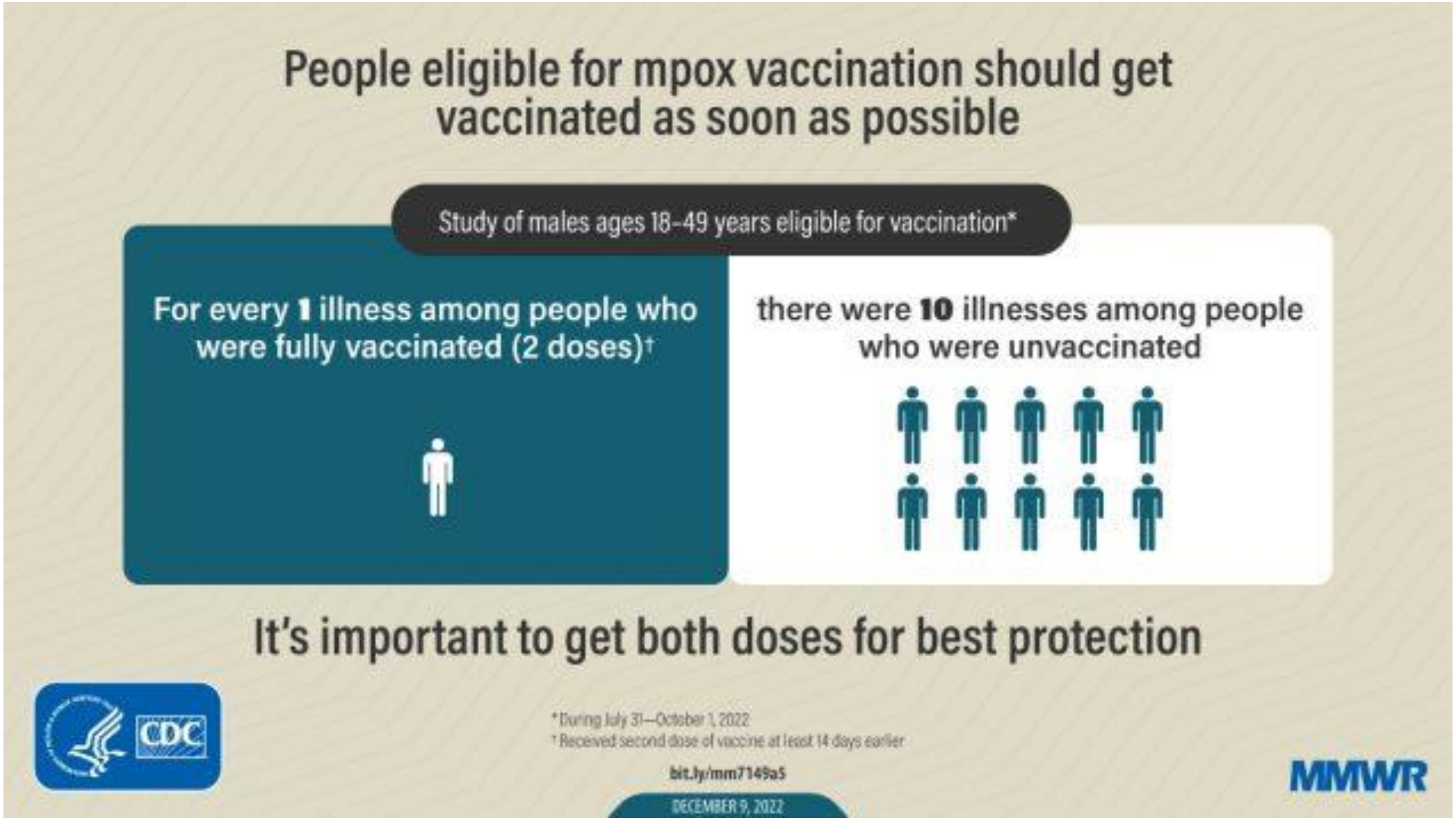
1,131,293

Doses Administered in the 57 U.S. Jurisdictions Reporting Data as of December 6 2022.

Total JYNNEOS Vaccine Second Doses and First Doses Reported to CDC



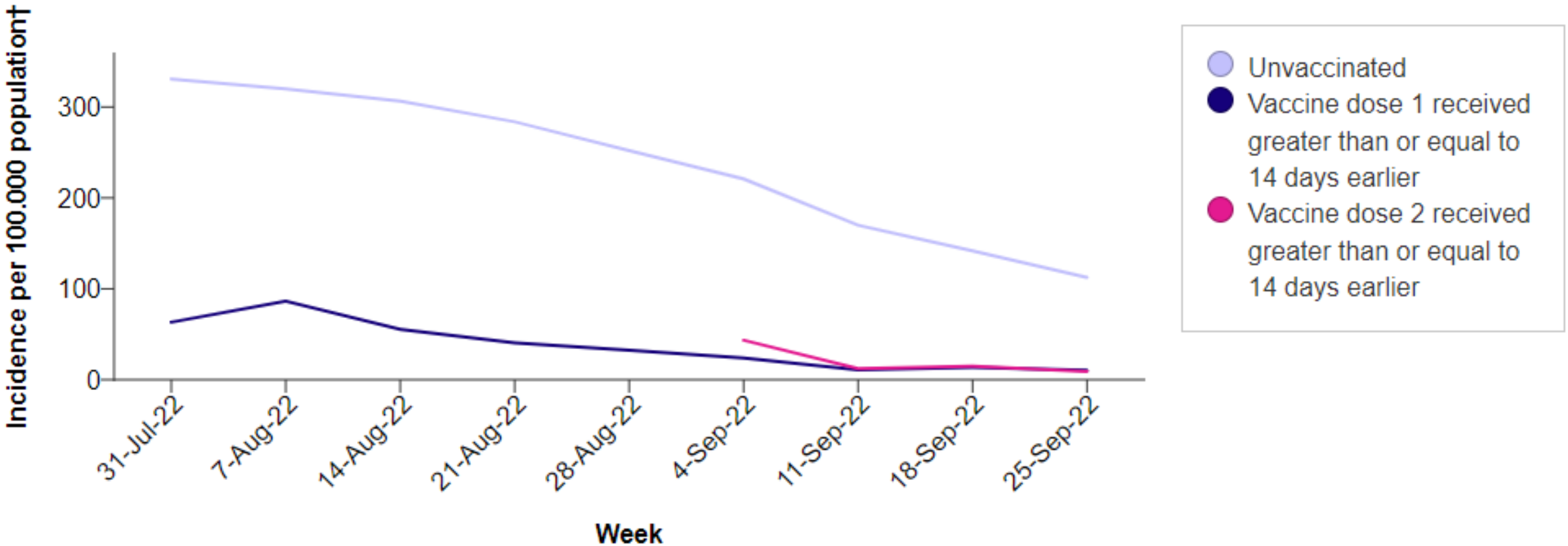
https://www.cdc.gov/poxvirus/monkeypox/response/2022/vaccines_data.html



https://www.cdc.gov/mmwr/volumes/71/wr/mm7149a5.htm?s_cid=mm7149a5_e&ACSTrackingID=USCDC_921-DM95304&ACSTrackingLabel=This%20Week%20in%20MMWR%20-%20Vol.%2071%2C%20December%209%2C%202022&deliveryName=USCDC_921-DM95304

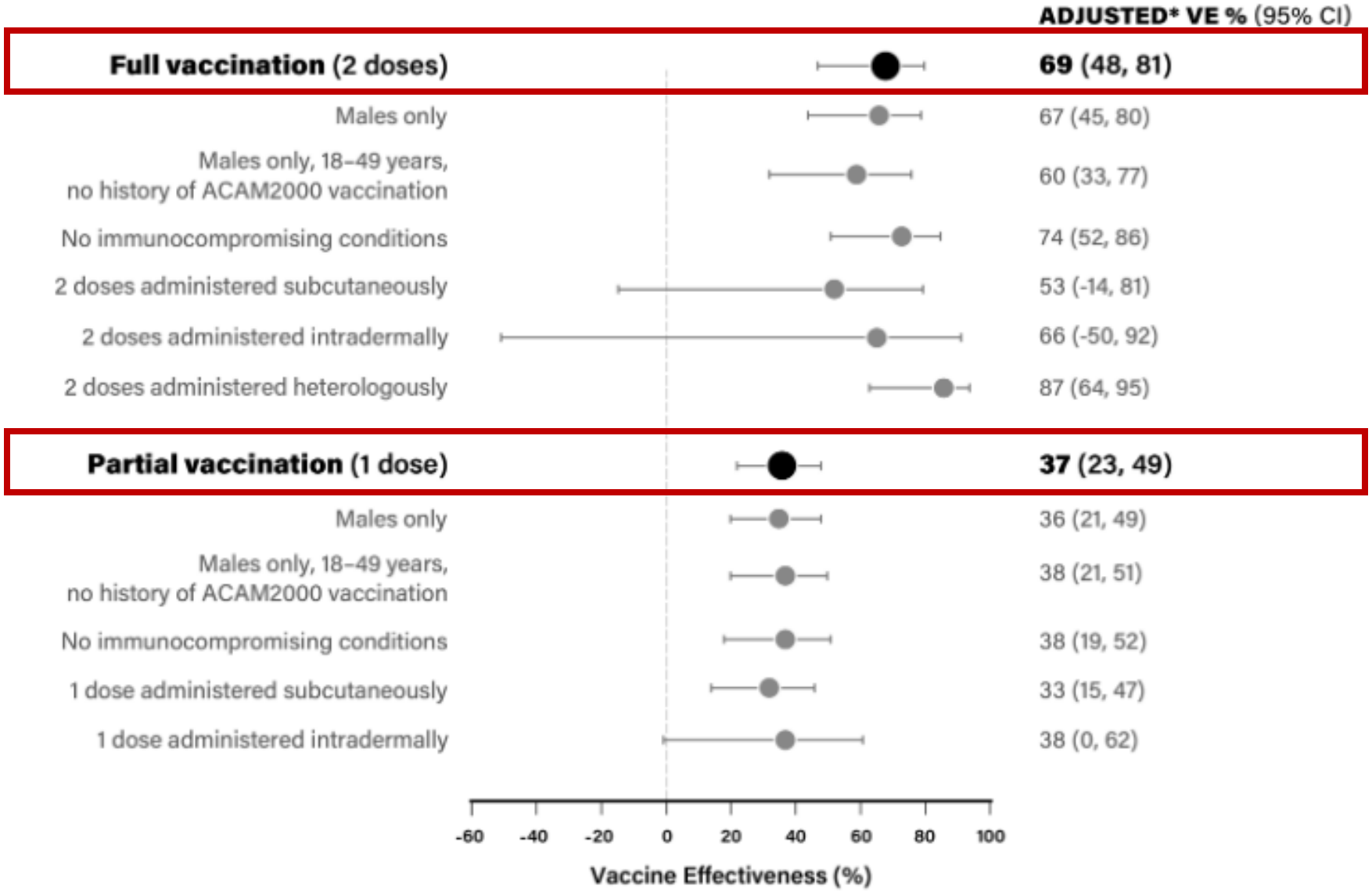
Rates of Mpox Cases by Vaccination Status*

July 31, 2022 – October 1, 2022 (43 U.S. jurisdictions)



https://www.cdc.gov/poxvirus/monkeypox/cases-data/mpx-vaccine-effectiveness.html

Preliminary JYNNEOS Vaccine Effectiveness Estimates Against Medically Attended Mpox Disease in the U.S., August 15, 2022 – October 29, 2022



https://www.cdc.gov/poxvirus/monkeypox/cases-data/mpx-JYENNOS-vaccine-effectiveness.html

Morbidity and Mortality Weekly Report (*MMWR*)

CDC

Safety Monitoring of JYNNEOS Vaccine During the 2022 Mpox Outbreak — United States, May 22–October 21, 2022

Weekly / December 9, 2022 / 71(49);1555–1559

"During May 22–October 21, 2022, nearly 1 million JYNNEOS doses were administered in the United States. **The vaccine safety profile was consistent with prelicensure studies. The most common adverse health events reported were nonserious** and included injection site reactions. Serious adverse events were rare among adults, and no serious adverse events have been identified among persons aged <18 years".

"Surveillance supports JYNNEOS vaccine safety"

https://www.cdc.gov/mmwr/volumes/71/wr/mm7149a4.htm?s_cid=mm7149a4_x

Of note:

On December 5, 2022, U.S. CDC updated the Mpox Vaccination Program Provider Agreement, and on **December 8, 2022, Maine Immunization Program sent the following communication to Maine Mpox Providers:**

"Jynneos vaccine **can once again be administered using the standard regimen subcutaneous route**, given at 0.5 mL per dose, **OR** providers can continue to use the alternative regimen, administered intradermally at 0.1 mL per dose. Healthcare providers should decide whether to offer the intradermal or subcutaneous regimen based on balancing optimal vaccine use and acceptance, feasibility of administration, and available vaccine supply. "

Resources

Follow-up questions
- 1-800-821-5821
- Disease.reporting@maine.gov
- MeCDC.HAI@maine.gov

U.S. CDC Resources
- https://www.cdc.gov/poxvirus/mpox/clinicians/infection-control-healthcare.html
- https://www.cdc.gov/poxvirus/mpox/clinicians/monitoring.html
- https://www.cdc.gov/poxvirus/mpox/transmission.html
- https://www.cdc.gov/poxvirus/monkeypox/response/2022/world-map.html
- https://www.cdc.gov/poxvirus/monkeypox/response/2022/us-map.html
- https://www.cdc.gov/poxvirus/monkeypox/response/2022/mpox-trends.html
- https://www.cdc.gov/poxvirus/monkeypox/response/2022/demographics.html
- https://www.cdc.gov/poxvirus/monkeypox/response/2022/2022-lab-test.html
- https://www.cdc.gov/poxvirus/mpox/clinicians/clinical-recognition.html
- https://www.cdc.gov/poxvirus/mpox/interim-considerations/jynneos-vaccine.html
- https://www.cdc.gov/std/treatment-guidelines/default.htm
- https://www.cdc.gov/poxvirus/mpox/clinicians/people-with-HIV.html

Maine CDC Resources
- https://www.maine.gov/dhhs/mecdc/infectious-disease/epi/zoonotic/mpox.shtml
- https://www.maine.gov/dhhs/mecdc/infectious-disease/epi/zoonotic/mpox-providers.shtml