

07/19/22

- Agenda
- Didactic: All Things Monkeypox: July 2022
- Case Discussions
- Open Discussion



Monkeypox is an Orthopox Virus

Monkeypox was first discovered in 1958 when two outbreaks of a pox-like disease occurred in colonies of monkeys kept for research, hence the name 'monkeypox.' The first human case of monkeypox was recorded in 1970 in the Democratic Republic of Congo during a period of intensified effort to eliminate smallpox. Since then monkeypox has been reported in humans in other central and western African countries.



Monkeypox is a rare disease that is caused by infection with monkeypox virus.



Background

- Monkeypox is endemic in several African countries
- From 2018 to mid-May 2022, 9 imported cases of monkeypox to non-endemic countries
 - United States (2)
 - United Kingdom (5)
 - Israel (1)
 - Singapore (1)
- No flight contacts developed infection
- One healthcare worker developed monkeypox (UK) and 2 family members acquired monkeypox (UK)

Source: https://www.cdc.gov/poxvirus/monkeypox/pdf/What-Clinicians-Need-to-Knowabout-Monkeypox-6-21-2022.pdf



HAN Health Update: June 14, 2022*

- Alerts healthcare providers about 2 emerging issues:
 - Symptoms and disease course that differ from what has been seen in past outbreaks in West and Central Africa
 - Limited number of cases reported in people who had no international travel (often called "community cases").
- These issues raise concern that some infections in the United States may not be recognized and tested
- Updates May 22 HAN advisory with expanded case definition
 - New definition intends to encourage testing for monkeypox

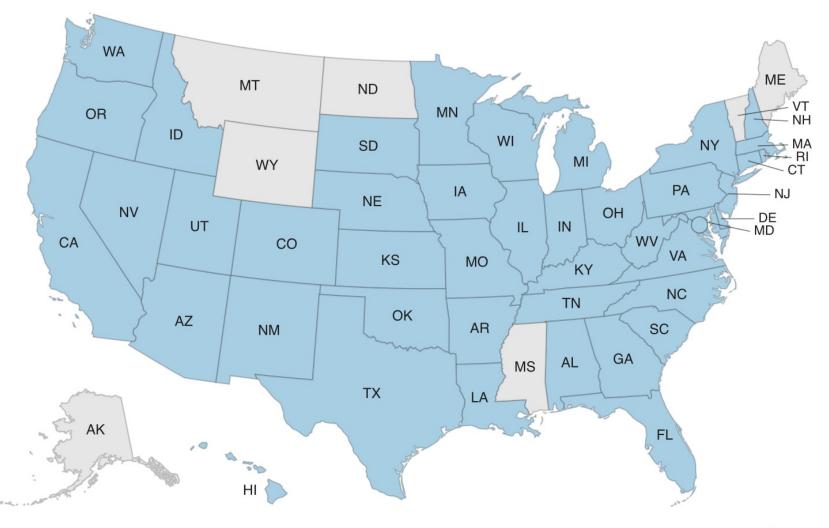






2022 U.S. Map & Case Count

Updated July 18, 2022 Print





Territories PR

Case Count by State of Residence

State	Numt
Alabama	2
Arizona	12
Arkansas	2
California	267
Colorado	22
Connecticut	14
Delaware	1
District Of Columbia	108
Florida	180
Georgia	110
🔵 Hawaii	8
🔵 Idaho	1
Illinois	200
Indiana	11
Iowa	3
Kansas	1
Kentucky	3



L	Louisiana	8
	 Maryland 	46
	Massachusetts	51
	 Michigan 	14
	Minnesota	13
	Missouri	4
	Nebraska	4
	Nevada	6
	New Hampshire	1
	New Jersey	31
	New Mexico	6
	New York	521
	North Carolina	13
	Ohio	7
	Oklahoma	3
Ĺ	Oregon	21
	Pennsylvania	61
	Puerto Rico	7
	Rhode Island	6
	 South Carolina 	5

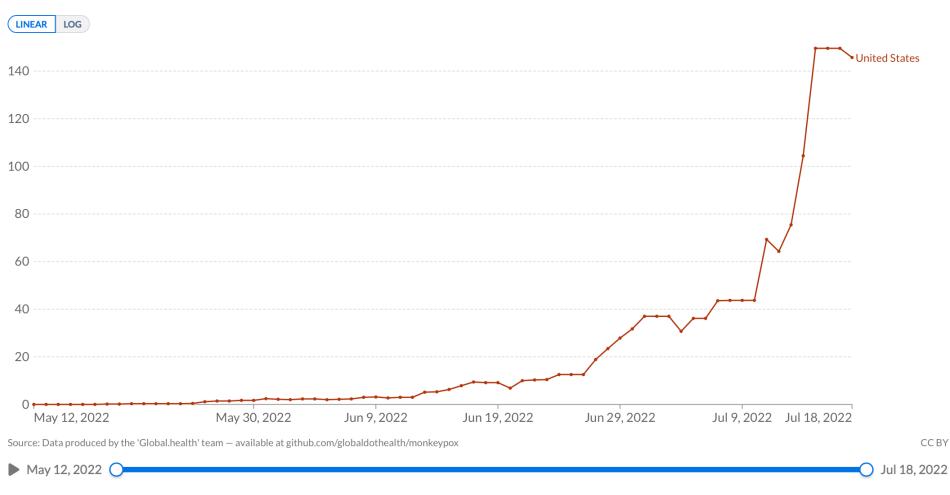


South Dakota	1
Tennessee	8
Texas	80
Utah	13
Virginia	44
Washington	43
West Virginia	1
 Wisconsin 	6



Monkeypox: Daily confirmed cases

7-day rolling average

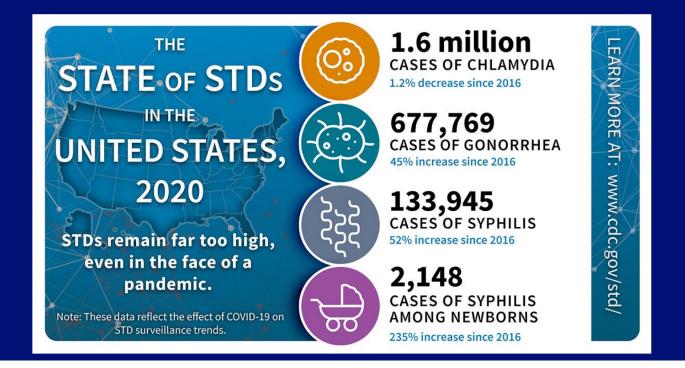






Our World in Data

2.4 million cases of chlamydia, gonorrhea, and syphilis were reported in the first year of the COVID-19 pandemic



Source: https://www.cdc.gov/poxvirus/monkeypox/pdf/What-Clinicians-Need-to-Knowabout-Monkeypox-6-21-2022.pdf



2022 Monkeypox Outbreak Global Map

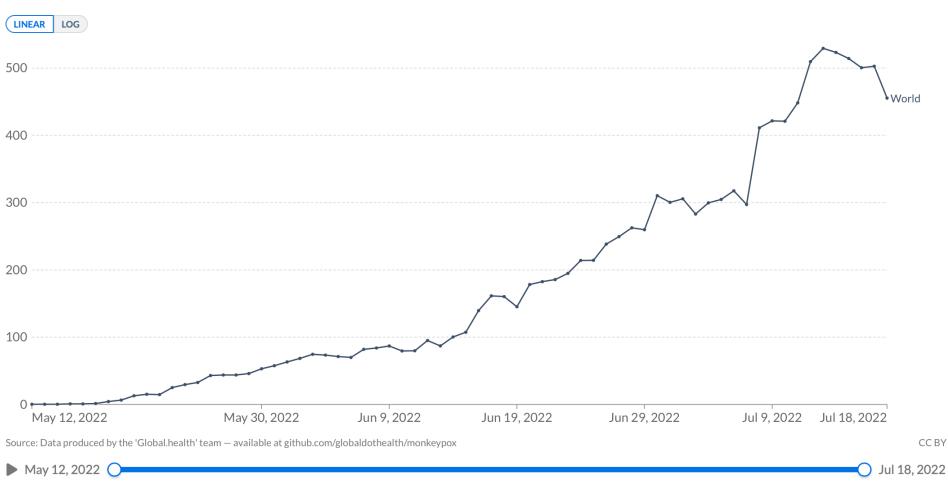
Updated June 21, 2022 Print





Monkeypox: Daily confirmed cases

7-day rolling average



Source: https://ourworldindata.org/monkeypox



Our World in Data

Post Exposure Prophylaxis

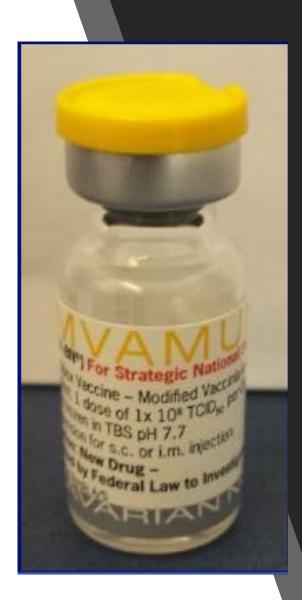
- For high risk exposed individuals with known contact
 - JYNNEOS vaccine (approved for smallpox & monkeypox in adults > 18 years old)
 - give within 4 days of exposure but up to 2 weeks
 - ACAM2000 (approved for smallpox, replication competent)
 - Vaccinia immunoglobulin (immunosuppressed)

People who should get Pre-exposure Prophylaxis include:

CDC recommends vaccination for people who have been exposed to monkeypox and people who are at higher risk of being exposed to monkeypox, including:

- People who have been identified by public health officials as a contact of someone with monkeypox
- People who may have been exposed to monkeypox, such as:
 - People who are aware that one of their sexual partners in the past 2 weeks has been diagnosed with monkeypox
 - People who had multiple sexual partners in the past 2 weeks in an area with known monkeypox
- People <u>whose jobs may expose them to orthopoxviruses</u>, such as:
 - Laboratory workers who perform testing for orthopoxviruses
 - Laboratory workers who handle cultures or animals with orthopoxviruses
 - Some designated healthcare or public health workers

https://www.cdc.gov/poxvirus/monkeypox/prevention.html



Vaccine

JYNNEOS[™] is administered as a live virus that is non-replicating.

- administered as 2 subcutaneous injections 4 weeks apart.

There is no visible "take" and as a result, no risk for spread to other parts of the body or other people.

 considered vaccinated until 2 weeks after they receive the second dose of the vaccine.

Past data suggests that the smallpox vaccine is at least 85% effective in preventing monkeypox.

The effectiveness of JYNNEOS[™] against monkeypox was concluded from a clinical study on the immunogenicity of JYNNEOS and efficacy data from animal studies.

https://www.fda.gov/media/131078/download

Treatment

No specific treatment for monkeypox BUT antivirals used for smallpox may prove beneficial

Tecovirimat - Expanded Access Investigational New Drug Protocol

- Cidofovir
 - shown to be effective against orthopoxviruses in *in vitro*/animal studies

Vaccinia immune globulin IV

 considered for prophylactic use in an exposed person with severe immunodeficiency in T-cell function

State and territorial health authorities can direct their requests for medical countermeasures for the treatment of monkeypox to the CDC Emergency Operations Center (770-488-7100). https://www.cdc.gov/poxvirus/monkeypox/treatment.html

What is tecovirimat?

F2 G4

FDA approved: treatment of smallpox in adults and children (weighing at least 3 kg)

-targets and inhibits the activity of an orthopoxvirus protein that prevents the formation enveloped virions that is necessary for dissemination of virus.

No data for treating monkeypox infections in people -studies using a variety of animal species have shown that tecovirimat is effective in treating disease caused by

orthopoxviruses

-available as a pill or an injection

The most frequently reported adverse reactions were headache and nausea

https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/214518s000lbl.pdf

Treatment Indication

People with severe disease (e.g., hemorrhagic disease, confluent lesions, sepsis, encephalitis, or other conditions requiring hospitalization)

- •People who may be at high risk of severe disease:
 - People with immunocompromise
 - •Pediatric populations, particularly patients younger than 8 years of age
 - •People with a history or presence of atopic dermatitis, persons with other active exfoliative skin conditions
 - Pregnant or breastfeeding women
 - •People with one or more complications (e.g., secondary bacterial skin infection; gastroenteritis with severe nausea/vomiting, diarrhea, or dehydration; bronchopneumonia; concurrent disease or other comorbidities)

People with monkeypox virus aberrant infections that include accidental implantation in eyes, mouth, or other anatomical areas where monkeypox virus infection might constitute a special hazard (e.g., the genitals or anus)

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

How do you get the drug?

- FDA Form 1572. One signed 1572 per facility suffices for all tecovirimat treatments administered under the EA-IND at the same facility.
- Informed consent. Obtain prior to treatment.
- Patient intake form.
- Adverse event form. Life-threatening or serious adverse events associated with TPOXX use should be reported to CDC (<u>regaffairs@cdc.gov</u>) within 24 hours of occurrence, or as soon as possible.
- **Outpatient Case Report Form.** Provides clinical progress of patients during TPOXX therapy (e.g., at Day 7). If the patient's clinical condition necessitates performing clinical labs, please include a copy of the results.
- **Post-TPOXX Treatment Form.** Provide clinical outcomes information after completion of treatment.

Obtaining and Using TPOXX (Tecovirimat) | Monkeypox | Poxvirus | CDC



Resources

<u>CDC, "What Clinicians Need to Know about Monkeypox</u> (June 2022):

<u>https://www.cdc.gov/poxvirus/monkeypox/pdf/What-Clinicians-Need-to-Know-about-Monkeypox-6-21-2022.pdf</u>

UW Clinical Virology Lab: <u>https://testguide.labmed.uw.edu/public/view/MPXQLT</u>

<u>https://www.cdc.gov/mmwr/volumes/71/wr/mm7123</u>
 <u>e1.htm</u>

