



Monkeypox Vaccine Work Group

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Chair, ACIP Monkeypox Vaccine WG

ACIP Meeting

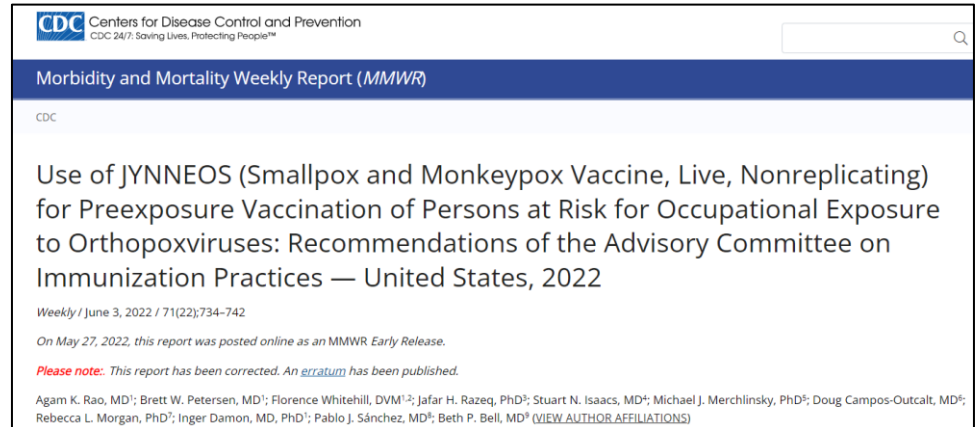
October 20, 2022

Monkeypox

- Rare, sometimes life-threatening zoonotic infection
- Endemic in parts of west and central Africa
- Caused by monkeypox virus (which is an orthopoxvirus)
- Can spread from infected animals to people and then person-to-person
 - Respiratory secretions
 - Skin-to-skin contact with infected bodily fluids (e.g., fluid from lesions)
 - Fomites (e.g., shared towels, clothing, and bedding)

2021 ACIP Orthopoxvirus Vaccine Vote

- Use of orthopoxvirus vaccine, JYNNEOS, (licensed in 2019) for pre-exposure vaccination of people at occupational risk for orthopoxvirus exposures
- WG meetings 2019–2021
- Recommendations published June 3, 2022



The image is a screenshot of a CDC Morbidity and Mortality Weekly Report (MMWR) article. At the top left is the CDC logo with the text 'Centers for Disease Control and Prevention' and the tagline 'CDC 24/7: Saving Lives. Protecting People™'. To the right is a search bar. Below the header is a blue bar with the text 'Morbidity and Mortality Weekly Report (MMWR)'. The main content area has a light blue background and contains the following text: 'cdc', 'Use of JYNNEOS (Smallpox and Monkeypox Vaccine, Live, Nonreplicating) for Preexposure Vaccination of Persons at Risk for Occupational Exposure to Orthopoxviruses: Recommendations of the Advisory Committee on Immunization Practices — United States, 2022', 'Weekly / June 3, 2022 / 71(22);734–742', 'On May 27, 2022, this report was posted online as an MMWR Early Release.', 'Please note: This report has been corrected. An [erratum](#) has been published.', and a list of authors: 'Agam K. Rao, MD¹; Brett W. Petersen, MD¹; Florence Whitehill, DVM^{1,2}; Jafar H. Razeq, PhD³; Stuart N. Isaacs, MD⁴; Michael J. Merchlinsky, PhD⁵; Doug Campos-Outcalt, MD⁶; Rebecca L. Morgan, PhD⁷; Inger Damon, MD, PhD⁸; Pablo J. Sánchez, MD⁹; Beth P. Bell, MD⁹ (VIEW AUTHOR AFFILIATIONS)'. The bottom of the page features a decorative bar with colored segments in orange, green, purple, and blue.

ACIP Votes About Primary Vaccination with JYNNEOS

- Use of JYNNEOS as an alternative to ACAM2000 for research laboratory personnel*, clinical laboratory personnel[†] performing diagnostic testing for orthopoxviruses, and for designated response team members at risk for occupational exposure to orthopoxviruses[§]
- Use of JYNNEOS based on shared clinical decision-making, as an alternative to ACAM2000 for healthcare personnel who administer ACAM2000 or care for patients infected with replication-competent orthopoxviruses

*Research laboratory personnel are those who directly handle 1) cultures or 2) animals contaminated or infected with replication-competent vaccinia virus, recombinant vaccinia viruses derived from replication-competent vaccinia strains (i.e., those that are capable of causing clinical infection and producing infectious virus in humans), or other orthopoxviruses that infect humans (e.g., monkeypox, cowpox, and variola)

[†]Clinical laboratory personnel who perform routine chemistry, hematology, and urinalysis testing, including for suspected or confirmed patients with orthopoxvirus infections, are not included in this recommendation as their risk for exposure is very low

[§]Public health authorities, at their own discretion, may approve a cohort of healthcare and/or public health personnel to receive primary vaccination against orthopoxviruses for preparedness purposes (e.g., first responders who might participate in a smallpox or monkeypox outbreak)

JYNNEOS

- JYNNEOS is an attenuated, non-replicating live virus vaccine produced from the strain Modified Vaccinia Ankara-Bavarian Nordic (MVA-BN)
 - Also known as IMVAMUNE, IMVANEX, MVA
- Licensed by FDA in September 2019 for prevention of smallpox and monkeypox disease in adults 18 years of age and older
- Series of two doses administered 28 days (4 weeks) apart

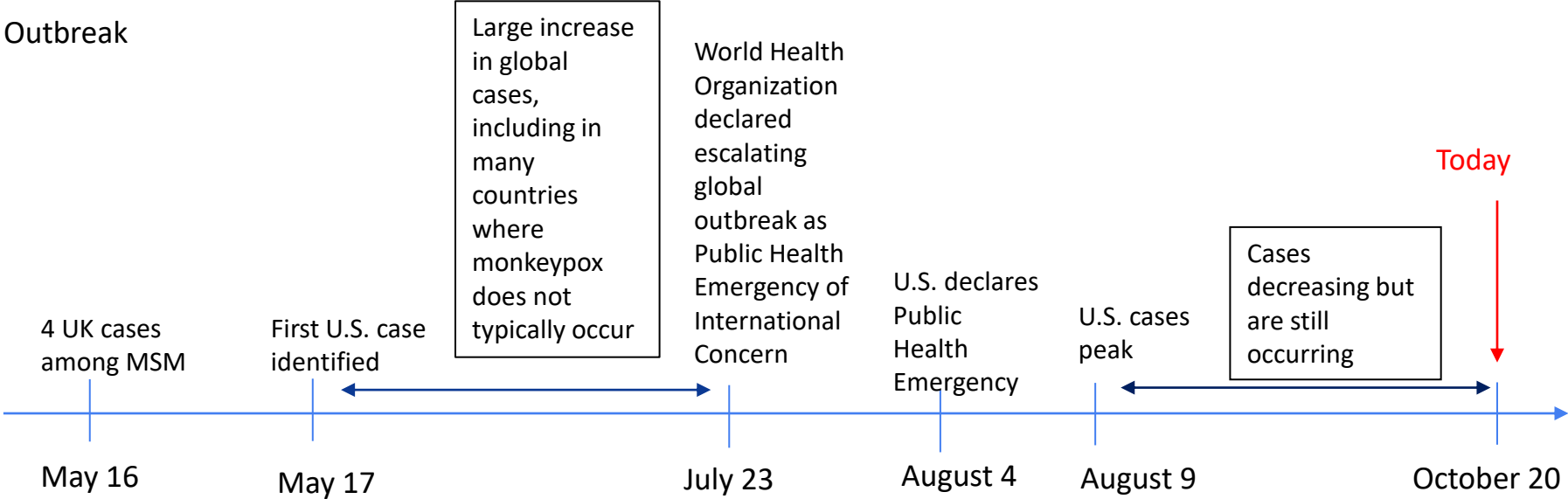
<https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/jynneos-vaccine.html>

JYNNOS Administration

- Standard regimen
 - Subcutaneous administration: volume of 0.5mL
 - Authorized for people aged <18 years under an Emergency Use Authorization
- Currently recommended regimen
 - Intradermal administration: Injection volume of 0.1mL
 - Results from a clinical study showed that the lower intradermal dose was immunologically non-inferior to the standard subcutaneous dose
 - Will facilitate more people being vaccinated

2022: Outbreak Predominantly Associated with MMSC*

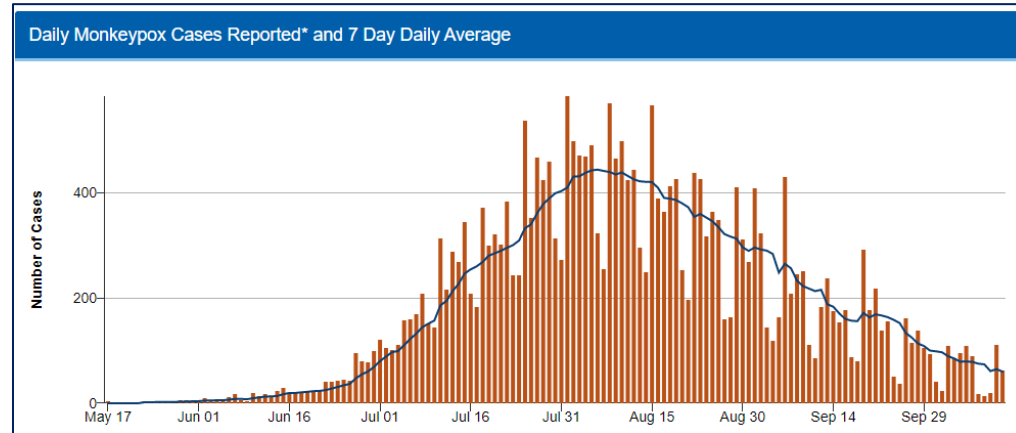
Outbreak



*Male-to-male sexual contact

Seven day average of U.S. cases since start of 2022 outbreak

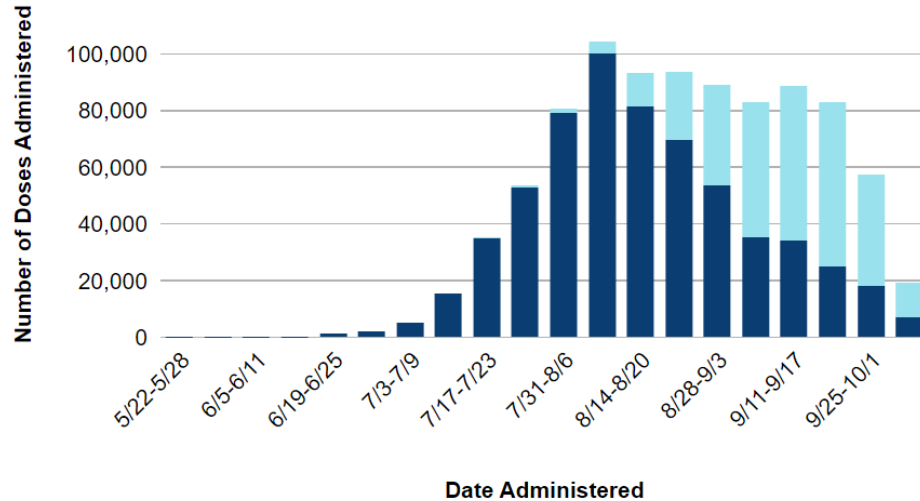
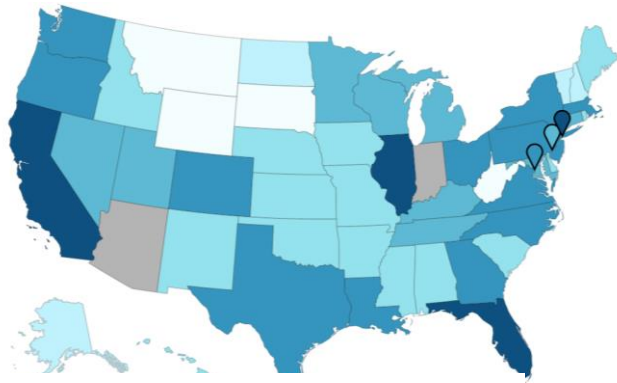
- Case counts decreasing after peak ~ August 9, 2022
- Male-to-male sexual contact (MMSC) most common
- Some cases in women, children, and men who do not report recent MMSC
- Demographic shift: white non-Hispanic → black and Hispanic



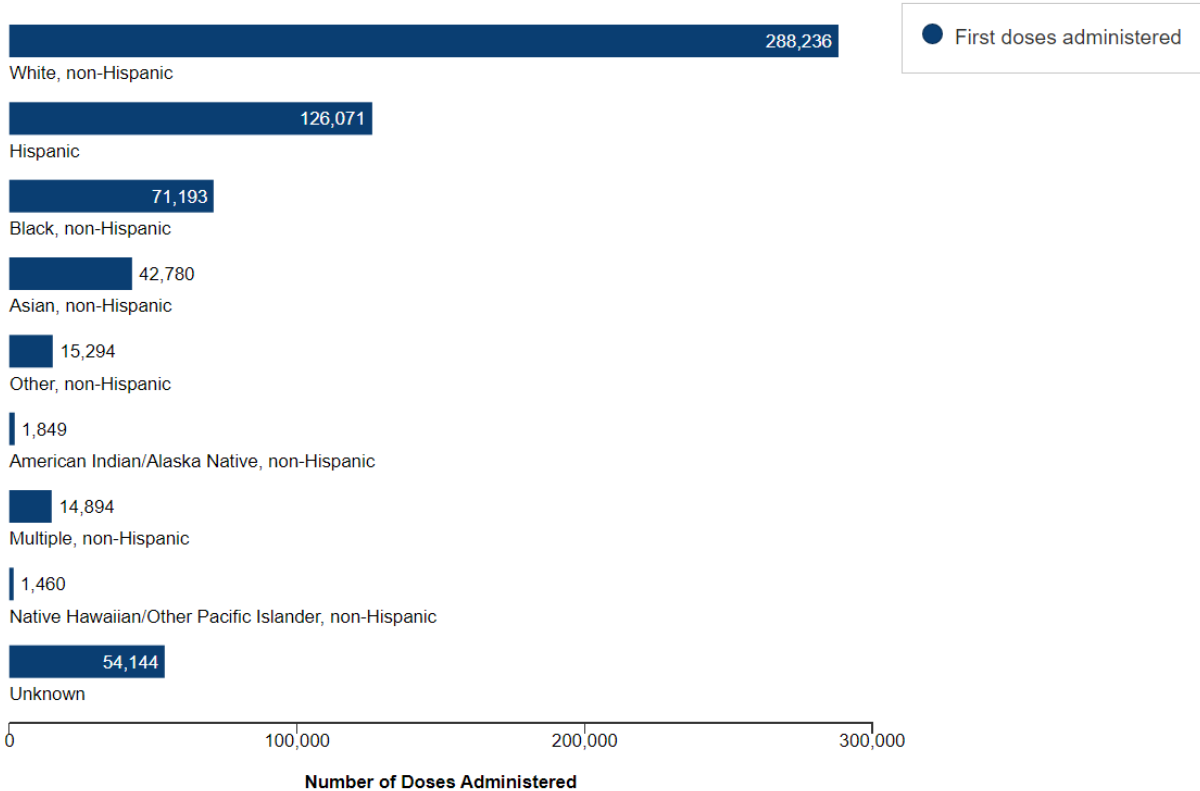
JYNNEOS Vaccine Doses Administered and Reported to CDC

906,325

Doses Administered in the 54 U.S. Jurisdictions Reporting Data as of October 11 2022.



First Vaccine Doses Administered by Race / Ethnicity



Vaccines to Prevent Orthopoxvirus Disease

- JYNNEOS
 - Approved for prevention of smallpox and monkeypox disease
 - Primary vaccine being used during current outbreak
 - Recommended by ACIP: primary vaccination and booster doses for certain people at occupational risk for orthopoxvirus infections
- ACAM2000
 - Approved for prevention of smallpox disease
 - Alternative to JYNNEOS
 - Recommended by ACIP: primary vaccination and booster doses for certain people at occupational risk for orthopoxvirus infections

Components of U.S. National Monkeypox Vaccination Strategy

Post-Exposure Prophylaxis (PEP)


Vaccination **after known exposure** to monkeypox

- People who are known contacts to someone with monkeypox who are identified by public health authorities, for example via case investigation, contact tracing, or risk exposure assessment

Expanded Post-Exposure Prophylaxis (PEP++)

Vaccination **after known or presumed** exposure to monkeypox

- People who are known contacts to someone with monkeypox who are identified by public health authorities, for example via case investigation, contact tracing, or risk exposure assessment
- People who are aware that a recent sex partner within the past 14 days was diagnosed with monkeypox
- Certain gay, bisexual, or other men who have sex with men, or transgender or nonbinary people, who have had any of the following within the past 14 days: sex with multiple partners (or group sex); sex at a commercial sex venue; or sex in association with an event, venue, or defined geographic area where monkeypox transmission is occurring



Pre-Exposure Prophylaxis (PrEP)

Vaccination **before exposure** to monkeypox

- People in certain occupational exposure risk groups*
- Gay, bisexual, and other men who have sex with men, transgender or nonbinary people who in the past 6 months have had
 - A new diagnosis of one or more nationally reportable sexually transmitted diseases (i.e., acute HIV, chancroid, chlamydia, gonorrhea, or syphilis)
 - More than one sex partner
- People who have had any of the following in the past 6 months:
 - Sex at a commercial sex venue
 - Sex in association with a large public event in a geographic area where monkeypox transmission is occurring
- Sexual partners of people with the above risks
- People who anticipate experiencing the above risks

<https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/overview.html>

U.S. Government Interim Recommendations for Monkeypox Vaccine Pre-exposure Prophylaxis (PrEP)

- People in certain occupational risk groups
- Gay, bisexual, and other men who have sex with men, transgender or nonbinary people who in the past 6 months have had
 - New diagnosis of one or more national reportable sexually transmitted diseases
 - More than one sex partner
- People who have had any of the following in the past 6 months
 - Sex at commercial sex venue
 - Sex in association with large public event in geographic area where monkeypox transmission is occurring
- Sexual partners of people with above risk
- People who anticipate experiencing above risks

ACIP WG Terms of Reference

- Purpose: During May 2022, a global monkeypox outbreak began, predominantly affecting men who have sex with men (MSM). WG will review available data to inform monkeypox vaccine policy, including recommendations for use of these vaccines in U.S. population during ongoing outbreak
- Topics under discussion:
 - Review epidemiology of monkeypox virus infection in United States
 - Evaluate safety and effectiveness of vaccines licensed to prevent monkeypox
 - Assess risk-benefit balance for use of vaccines during ongoing outbreak
 - Identify areas where additional data are needed to inform recommendations
 - Develop monkeypox vaccine policy options

First WG Topic

Further consideration of populations for which JYNNEOS monkeypox vaccine should be offered as pre-exposure prophylaxis (PrEP)

Data to Be Reviewed by WG

- Public health problem
- Vaccine effectiveness for subcutaneous and intradermal administration
- Vaccine safety for subcutaneous and intradermal administration
- Values and acceptability of vaccine to affected population
- Feasibility and resource use involved in PrEP expansion
- Health equity considerations
- Timeline to be determined

WG members

ACIP Members

Pablo Sánchez

Beth Bell

Ex Officio and Liaison Members

CSTE: Chris Hahn / Paul Cieslak

ASTHO: Ericka McGowan

NACHO: Philip Huang

FDA: Sixun Yang, Clement

Meseda & Alonzo García

ACOG: Howard Minkoff

AAP: Jim Campbell

IDSA: Shireesha Dhanireddy / Rajesh Gandhi

NACI- Nicole Forbes / Oliver Baclic

APHL: Jafar Razeq

NIH: Janet Lathey / Kimberly Taylor

AIM: Matthew Clark

Invited Consultants

Subject matter experts: Inger Damon, Stuart Isaacs, Mike Merchlinsky & Amanda Zarrabian (HHS/BARDA)

Clinician experts in STIs, HIV, pediatrics, maternal vaccination, vaccine safety, health equity, smallpox vaccination strategies, occupational health

Red indicates persons who members of 2019-2021 ACIP orthopoxvirus WG

Clinician experts

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(adult and peds):

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Jeanne MARRAZZO

Pablo Tebas

Vince Marconi

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Bonnie Maldonado

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Kathy Edwards

Health equity, vaccination strategies including for smallpox:

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Thank you!

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

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

