

The logo consists of the letters 'MPOX' in a white, sans-serif font, set against a background of vertical bars in shades of orange and red.

Mpox Vaccine Implementation and Interim Clinical Considerations

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2022 Multinational Mpox Response

Centers for Disease Control and Prevention

Advisory Committee on Immunization Practices

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www.cdc.gov/mpox

Interim Clinical Considerations (ICC) is a living document

- **Continued emphasis on vaccination:** Mpox vaccination should continue to be offered to people with the highest potential for exposure to mpox.
- **Updated guidance:** People with HIV infection or other causes of immunosuppression who have had recent or anticipate potential mpox exposure should be vaccinated against mpox.
- **New emphasis on inclusion of adolescents:** The principal risk group was reworded as “Gay, bisexual, and other men who have sex with men, and transgender or nonbinary people (including adolescents who fall into any of the aforementioned categories) ... “

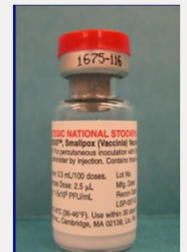
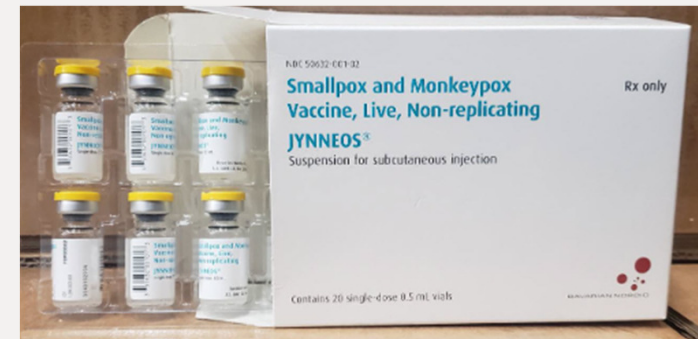
Available Vaccines for Mpox

- JYNNEOS

- Primary vaccine for mpox outbreak in U.S.
- Licensed in the U.S. for subcutaneous administration in individuals 18 years or older
- FDA Expanded Use Authorization (EUA) in Aug 2022
 - Intradermal administration for individuals 18+
 - Subcutaneous administration for individuals <18 at high risk for mpox infection

- ACAM2000

- Available, but not used during current outbreak
- Higher risk of serious adverse events, including myocarditis



U.S. National Mpox Vaccine Strategy

- U.S. National Mpox Vaccine Strategy – June 2022
 - Vaccinate and protect people at risk
 - Prioritize vaccine allocations based on reported case numbers
 - Provide guidance to health officials for planning and response
- Multiple federal agencies coordinating to implement mpox vaccine strategy
 - ASPR (SNS, BARDA), CDC, FDA



BRIEFING ROOM

FACT SHEET: Biden-Harris Administration's Monkeypox Outbreak Response

JUNE 28, 2022 • STATEMENTS AND RELEASES

Vaccination Strategies

Strategy	e o
Post-Exposure Prophylaxis (PEP)	Vaccination after known or presumed exposure to mpox
Vaccination Prior to Exposure	Vaccination <u>before</u> exposure to mpox

Post-Exposure Prophylaxis

- People who are known contacts to a person with mpox, and identified by public health authorities as a “contact” (for example, from case investigation, contact tracing, or risk exposure assessment); or
- People who are aware that a recent (within the past 14 days) sex partner was diagnosed with mpox; or
- Gay, bisexual, other men who have sex with men, and transgender or nonbinary people (includes adolescents) 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 mpox transmission is occurring

Vaccination prior to exposure to mpox virus

Offered to people with highest potential for exposure or **who anticipate potential exposure to mpox**, including:

- Gay, bisexual, and other men who have sex with men, and transgender or nonbinary people (including adolescents) who, within the **past 6 months**, have had:
 - A new diagnosis of one or more sexually transmitted diseases (e.g., chlamydia, gonorrhea, syphilis); or
 - More than one sex partner.
- People who have had any of the following in the **past 6 months**:
 - Sex at a commercial sex venue; or
 - Sex in association with a large public event in a geographic area where mpox transmission is occurring.
- Sexual partners of people with the above risks.
- People with HIV[†] infection or other causes of immunosuppression who have had recent or anticipate potential mpox exposure
- People in certain occupational exposure risk groups (laboratory personnel working with orthopoxviruses)

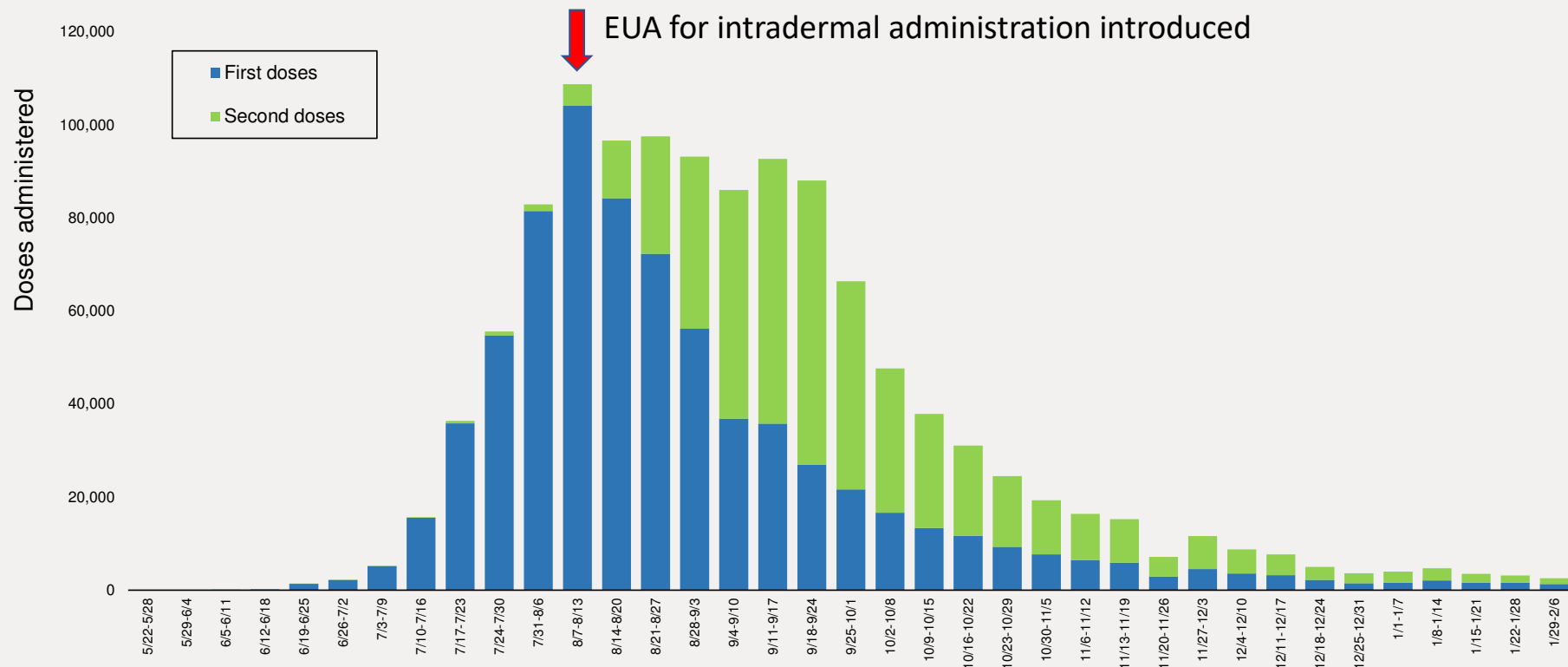
*People at risk for occupational exposure to orthopoxviruses include research laboratory personnel working with orthopoxviruses, clinical laboratory personnel performing diagnostic testing for orthopoxviruses, and orthopoxvirus and health care worker response teams designated by appropriate public health and antiterror authorities. (see [ACIP recommendations](#)).
[†]JYNNEOS is considered safe in persons with HIV infection, although effectiveness may be lower among severely immunocompromised individuals. ACAM2000 should not be used in certain people, including those with advanced HIV disease or other causes of immunosuppression, who are pregnant, or who have certain heart conditions.

CDC Health Equity Considerations Utilized in Mpox National Vaccination Strategy

- Engage people from affected communities in planning and design
- Use non-stigmatizing, plain language
- Reiterate privacy of information and how data will be used
- Engage diverse partners already working with special populations
- Bring vaccines to where people are: pop-up events, mobile outreach
- To improve accessibility, offer multiple opportunities and times
- Leverage clinical venues: STI clinics, LGBTQ+ health centers
- Use multiple channels to advertise and book appointments
- Minimize systems that are first-come, first-served

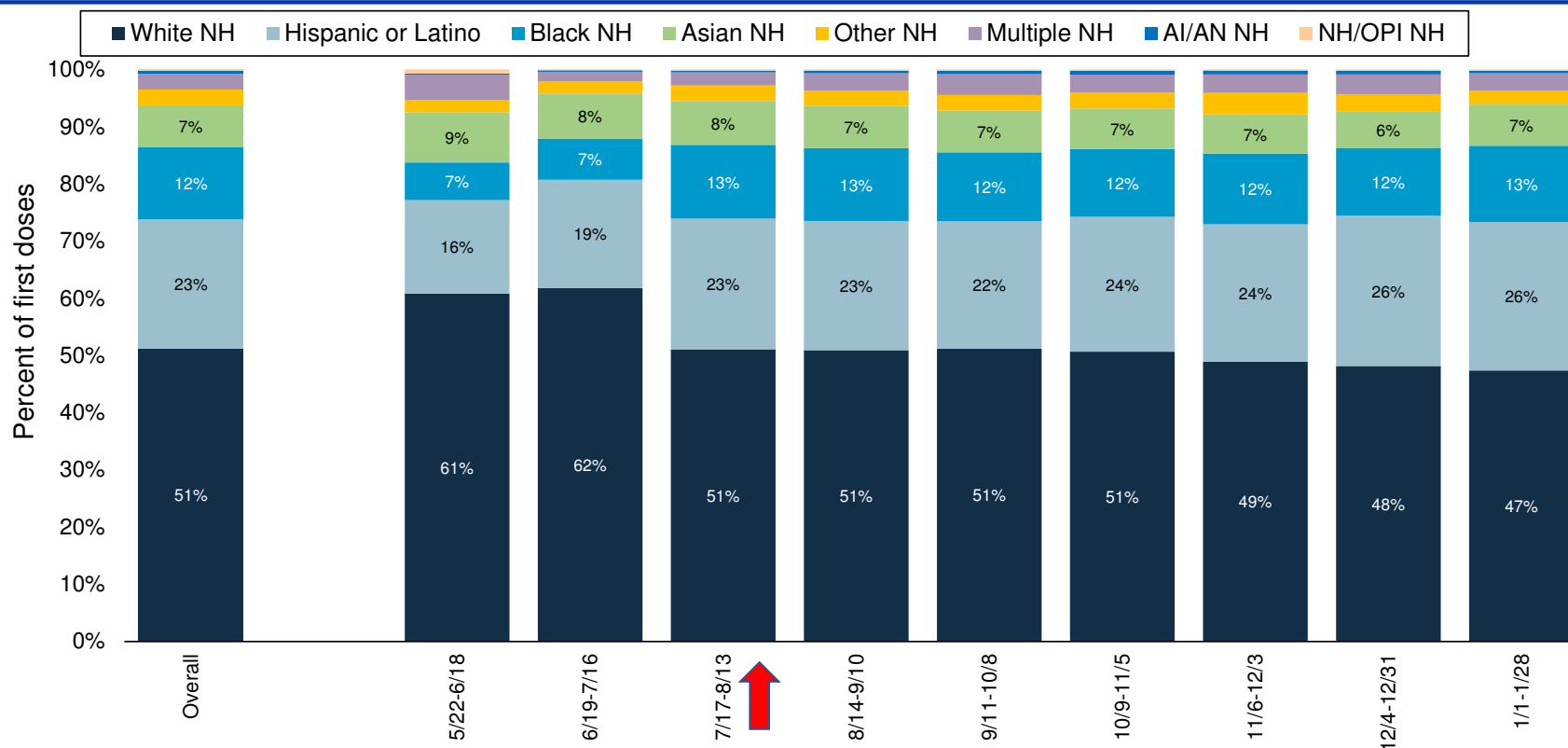
Total JYNNEOS Vaccine Doses Administered and Reported to CDC as of Feb 7, 2023

1,185,907 doses* administered and reported to CDC since May 20, 2022



Vaccine First Doses Administered, by Race/Ethnicity

Data Reported to CDC as of January 31, 2023



NH=non-Hispanic, AI/AN=American Indian/Alaska Native, NH/OPI=Native Hawaiian/Other Pacific Islander. Weeks where n<30 are not shown. Does not include recipients of Unknown race/ethnicity.

Source: CDC Immunization Data Lake. Data submitted as of January 31, 2023, 4:00 am ET.

Data are Provisional Until Officially Released by the CDC - For Internal Use Only (FIUO) - For Official Use Only (FOUO) - Sensitive But Unclassified (SBU) - Not for Further Distribution

Elements of Mpox Vaccine Implementation in the U.S. during this Outbreak

- Vaccine strategies and implementation plans were adapted by local jurisdictional health departments for their specific settings
- Vaccine eligibility criteria were modified as the epidemiology evolved and new scientific findings emerged, and were adjusted for local context
 - Examples: Inclusion of sex workers; removing sexual orientation labels from eligibility criteria, reducing potential stigma by allowing participant to self-attest to eligibility
- Recognition that mpox vaccination offered in context of broader prevention activities and sexual health care may increase access and coverage
- Critical role of community organizations as trusted messengers, facilitating increased access to vaccination
- Need dedicated resources for reporting vaccine inventory and administration data
- Require vaccine status, date of vaccination on mpox case reporting or link cases with state immunization inventory system to evaluate vaccine performance
- Include race and ethnicity data on vaccination reports, including on reports shared with CDC

Implementation challenges and solutions

- Limited vaccine supply at the peak of the outbreak in mid-July when demand was highest
 - EUA for intradermal route of administration increased vaccine supply by 300%
- Limited ability to ship directly to providers
 - May to September, shipments limited to 5 per week; by mid Sept, up to 150 shipments/week
- Switch to intradermal administration required skills training and additional supplies
 - On average, jurisdictions began to implement within 2-3 weeks of EUA
- Initially, health departments and public clinics were the primary vaccine providers (>50% of all vaccinations)
 - Increasing role of STI, HIV care providers, pharmacies