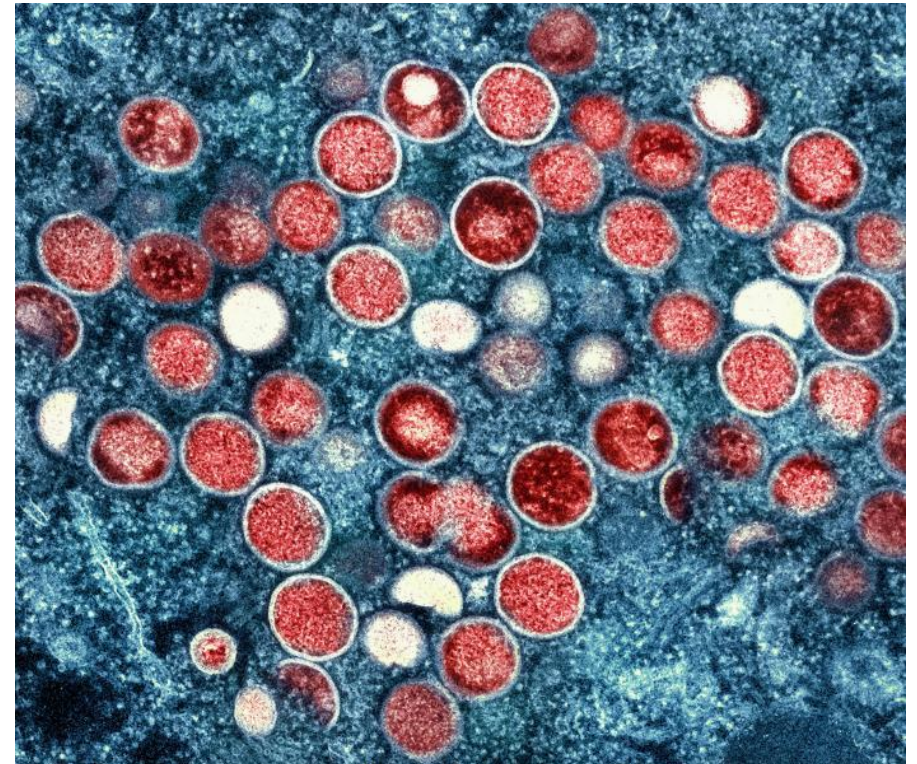


Challenges of Mpox Vaccination—Frequently Asked Questions in the United States, 2024

Centers for Disease Control and Prevention



IDWeek

October 17, 2024

Frequently asked questions about JYNNEOS vaccination

- Clade II mpox
 - Why aren't mpox vaccinations recommended for people who recovered from mpox?
 - Should booster doses be given to people who received both vaccine doses during 2022?
 - Why are booster doses recommended for certain people at occupational risk for exposure to mpox but not people vaccinated as part of the ongoing global clade II outbreak?
 - Should healthcare personnel be vaccinated?
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 - Why aren't vaccinations recommended for children who travel?

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Mpox clade II epi-curve—United States, May 1, 2022-September 30, 2024, N= 33,972



Men who have sex with men disproportionately impacted
Life-threatening infections still occurring

Vaccination recommended: Persons at risk because of the ongoing clade II global outbreak

- 1. Gay, bisexual, and other men who have sex with men, 2. transgender people or 3. nonbinary people who, in the past 6 months, have had one of the following
 - New diagnosis of ≥ 1 sexually transmitted disease
 - More than one sex partner
 - Sex at a commercial venue
 - Sex in association with a large public event in a geographic area where mpox transmission is occurring
- Sexual partners of persons with the risks described above
- Persons who anticipate experiencing any of the above

*<https://www.cdc.gov/poxvirus/mpox/vaccines/vaccine-recommendations.html>

Table 1 Recommended Adult Immunization Schedule by Age Group, United States, 2024

Vaccine	19–26 years	27–49 years	50–64 years	≥65 years
COVID-19	1 or more doses of updated (2023–2024 Formula) vaccine (See Notes)			
Influenza inactivated (IIV4) or Influenza recombinant (RIV4)	1 dose annually			
Influenza live, attenuated (LAIV4)	1 dose annually			
Respiratory Syncytial Virus (RSV)	Seasonal administration during pregnancy. See Notes.			≥60 years
Tetanus, diphtheria, pertussis (Tdap or Td)	1 dose Tdap each pregnancy; 1 dose Td/Tdap for wound management (see notes)			
	1 dose Tdap, then Td or Tdap booster every 10 years			
Measles, mumps, rubella (MMR)	1 or 2 doses depending on indication (if born in 1957 or later)			For healthcare personnel, see notes
Varicella (VAR)	2 doses (if born in 1980 or later)		2 doses	
Zoster recombinant (RZV)	2 doses for immunocompromising conditions (see notes)		2 doses	
Human papillomavirus (HPV)	2 or 3 doses depending on age at initial vaccination or condition	27 through 45 years		
Pneumococcal (PCV15, PCV20, PPSV23)				See Notes
				See Notes
Hepatitis A (HepA)	2, 3, or 4 doses depending on vaccine			
Hepatitis B (HepB)	2, 3, or 4 doses depending on vaccine or condition			
Meningococcal A, C, W, Y (MenACWY)	1 or 2 doses depending on indication, see notes for booster recommendations			
Meningococcal B (MenB)	19 through 23 years	2 or 3 doses depending on vaccine and indication, see notes for booster recommendations		
Haemophilus influenzae type b (Hib)	1 or 3 doses depending on indication			
Mpox				

Recommended vaccination for adults who meet age requirement, lack documentation of vaccination, or lack evidence of immunity

Recommended vaccination for adults with an additional risk factor or another indication

Recommended vaccination based on shared clinical decision-making

No recommendation/ Not applicable

Mpox vaccine on routine immunization schedule

Mpox vaccination

Special situations

• **Any person at risk for Mpox infection:** 2-dose series, 28 days apart.

Risk factors for Mpox infection include:

- Persons who are gay, bisexual, and other MSM, transgender or nonbinary people who in the past 6 months have had:
 - A new diagnosis of at least 1 sexually transmitted disease
 - More than 1 sex partner
 - Sex at a commercial sex venue
 - Sex in association with a large public event in a geographic area where Mpox transmission is occurring
- Persons who are sexual partners of the persons described above
- Persons who anticipate experiencing any of the situations described above

www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf

Implementing vaccine recommendation

- People with mpox risk factors*
 - Did not previously have mpox **and**
 - Did not previously get 2 JYNNEOS vaccine doses
- People who have not yet received the 2nd vaccine dose (and never had mpox)
 - Should receive the dose 28 days after the first dose **or**
 - If more than 28 days have elapsed, receive the 2nd dose as soon as possible, regardless of the amount of time that has passed

*as defined in earlier slide

Why aren't vaccinations recommended for people who recovered from mpox?

Recovery from mpox confers protection that might be better than that provided from the vaccines

Mpox re-infections are rarer than breakthrough infections after 2 JYNNEOS doses

- Since 2022, CDC has investigated reported mpox re-infections
- Unpublished CDC data suggest mpox occurred in <0.001% of people in the United States who previously had mpox
- When re-infections occurred, they were typically milder than the initial infection
- There's therefore no benefit to vaccinating people who previously recovered from mpox

Should booster doses be given to people who received both vaccine doses during 2022?

Booster doses are not recommended at this time

Concerns about waning immunity

- Serologic studies have shown vaccine titers decrease a few months after vaccination
 - However, levels of circulating titers are not only marker of protection (e.g., cell-mediated immunity, innate immunity not measured)
 - Therefore, clinical significance of decreased titers unknown
- Breakthrough infections reported, including cluster in Chicago among fully vaccinated persons*
 - Cases attributed to frequent behaviors associated with mpox transmission, regardless of vaccine coverage
 - Similar clusters have been intermittently reported in other jurisdictions

*Faherty E, Holly T, Ogale Y et al. Investigation of an Mpox Outbreak Affecting Many Vaccinated Persons in Chicago, Illinois—March 2023-June 2023. Clin Infect Dis. 2024 Jul 19; 79(1): 122-129.

Recent data indicate sustained vaccine effectiveness

- Vaccine effectiveness in England during 2023
 - Estimated effectiveness of the 2-dose series was 80% indicating sustained protection*
 - Model suggests that more cases would have been observed in 2023 had duration of protection been only 2 years[†]
- Real world data^{§¶} about infections after 2 JYNNEOS doses in the United States has indicated breakthrough infections are rare nationally
 - In data through May 2024, despite clusters in some jurisdictions, these occurred in <1% of people fully vaccinated
 - Occurred at disparate time intervals after vaccination and milder

*Charles H, Thorley K, Turner C et al. Mpox Epidemiology and Vaccine Effectiveness, England, 2023; Emerg Infect Dis. 2024 Oct; 30 (10): 2145-2148

†Zhang X, Niyomsri S, Mandal S et al. Cost-effectiveness of Vaccination Strategies to Control Future Mpox Outbreaks in England. medRxiv 2024.08.20.24312301; doi: <https://doi.org/10.1101/2024.08.20.24312301>

§Guagliardo S, Kracalik I, Carter RJ et al. Monkeypox virus Infections After 2 Preexposure Doses of JYNNEOS Vaccine—United States, May 2022-May 2024. MMWR Morb Mortal Wkly Rep. 2024 May; 73 (20): 460-466.

¶ Cases for which vaccination data reported to CDC

Duration of long-term vaccine effectiveness unclear

- Unpublished data* suggest protection for at least 5 years after 2-dose primary series
 - Rapid and robust antibody response observed after vaccine
 - Response observed irrespective of circulating antibody levels before third vaccine dose; data indicate durable B cell memory
- MPXV (clade I) challenge studies in non-human primates (2.7 to 3 years after MVA/JYNNEOS primary vaccination) demonstrate protection regardless of level of circulating antibody[†]

*ClinicalTrials.gov ID NCT02977715 (<https://clinicaltrials.gov/study/NCT02977715?id=NCT02977715%20&rank=1>)

[†] Earl et al., Virology, 2007; Nigam et al., Virology, 2007

Booster doses

- Currently, no U.S. booster recommendations for the affected population
- U.K.'s national immunization guidance recommends most people with sexual risk factors receive a booster dose in 10 years, assuming mpox remains a public health problem*

*Green book: Immunisation against Infectious Diseases, Smallpox and mpox, chapter 29. 2024 September 12.

https://assets.publishing.service.gov.uk/media/66e2c8cce47cfc6de429d589/Green-Book-chapter-29_Smallpox-and-mpox_12September24.pdf

Why are booster doses recommended for certain people at occupational risk for exposure to mpox but not people vaccinated as part of the ongoing global clade II outbreak?

Unlike those exposed to mpox lesions, certain laboratorians are at risk for exposures to highly potent monkeypox virus (MPXV)

Similar to other national vaccine recommendations, circulating antibody levels are maintained at higher levels when there is increased risk for severe infection

Certain laboratorians have a high risk for severe infections

- MPXV Research laboratorians and certain MPXV clinical laboratorians*
 - May work with virus in concentrations 100-1000 times more than concentrations in mpox lesions
 - Occasionally experience needlestick accidents and other unusual virus exposures despite PPE
- Booster doses have always been recommended for certain laboratorians who are at occupational risk for exposure to orthopoxviruses
- Booster doses are recommended every 2 years
 - To ensure an evidence-based recommendation: Currently, no published data about the rapidity of an anamnestic response >2 years after the JYNNEOS primary series
 - maintain high level of circulating antibodies

*i.e., those performing orthopoxvirus and MPXV diagnostic testing

Should healthcare personnel be vaccinated?

**JYNNEOS is not recommended as a routine vaccination
for healthcare personnel**

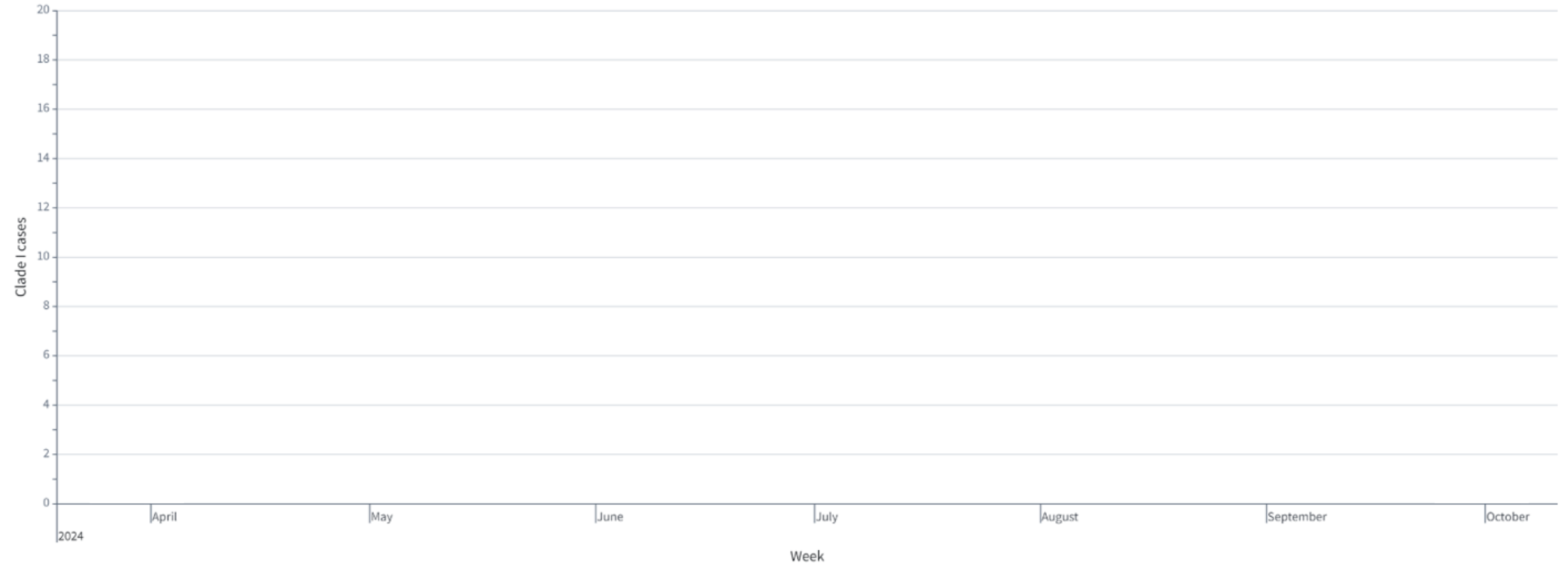
Guidance for healthcare personnel

- Mpox cases rare among healthcare personnel
 - Sharps injuries while unroofing lesions*
 - Suboptimal PPE
- Recommended infection prevention and control practices are effective
- Rare exceptions
 - Clinicians without reliable PPE caring for mpox patients as part of designated response team (e.g., via humanitarian aid groups)
 - Clinicians case-by-case based on site-and activity specific biosafety risk assessments (e.g., inadequate PPE)

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No clade I cases in the United States



Is the vaccine effective against clade I mpox?

**JYNNEOS is expected to protect against both clades
(and all sub-clades)**

Comparing SARS-CoV-2 to MPXV

- SARS-CoV-2
 - RNA virus: Single nucleotide changes (i.e., mutations) occur at fast rate
 - Single protein (i.e., spike protein) associated with entry into human cells
 - Risk for frequent and new variants with differing vaccine effectiveness
- MPXV
 - DNA virus: Mutations occur at slow rate
 - 17 proteins associated with entry into human cells; likelihood of all 17 proteins having mutation unlikely
 - Sub-clades probably not “new” but only newly recognized; vaccine effectiveness not impacted

Why isn't mpox vaccine effectiveness impacted?

- Part of virus associated with binding to antibodies >98% similar across all orthopoxviruses, including both clades (and all sub-clades) of MPXV
- Reminder: JYNNEOS comprised of vaccinia virus (not MPXV)
 - Vaccinia virus vaccines used to eradicate smallpox
 - JYNNEOS recommended for persons at occupational risk for exposure to any orthopoxviruses (not just MPXV)*

*Rao et al. ACIP recommendations.
MMWR 2022.

Should travelers get vaccinated?

Certain travelers are eligible for mpox vaccination

Recommendations for travelers*

- Risk low
- Counseling about risk reduction strategies
- Vaccination, irrespective of sexual orientation and gender identity, to travelers to certain countries[†] who anticipate any of the following during that travel:
 - Sex with a new partner
 - Sex at a commercial sex venue (such as a sex club or bathhouse)
 - Sex in exchange for money, goods, drugs, or other trade
 - Sex in association with a large public event (such as a rave, party, or festival)

*<https://emergency.cdc.gov/han/2024/han00516.asp>

[†]List of countries with sustained spread maintained on CDC website:

<https://www.cdc.gov/mpox/vaccines/index.html>; currently, the countries are Burundi, Central African Republic, Democratic Republic of the Congo, Republic of the Congo, Rwanda, and Uganda

Prevention Strategies for Mpox, including
Vaccinating People at Risk via Sexual Exposure,
for U.S. Travelers Visiting Countries with Clade I
Mpox Outbreaks

Print

  This is an official
HEALTH UPDATE

Distributed via the CDC Health Alert Network
September 23, 2024, 12:45 PM ET
CDCHAN-00516

**Why aren't vaccinations recommended for children
who travel?**

**Risk to U.S. travelers, including children, considered
low***

*Based on epidemiology available at this time

Epidemiology*

- True incidence of clade I cases unclear
 - Most cases not laboratory confirmed
 - Concurrent cases and outbreaks of infections confused with mpox (e.g., measles, chickenpox)
- Spread in endemic countries
 - From animals to people resulting; associated with a large number of cases in children
 - Sexual contact in adults
 - Human-to-human spread (including from adults to children) in crowded households or during caregiving
- Spread in non-endemic countries
 - Primarily via sex during travel
 - Human-to-human spread (including from adults to children) via household contact
 - Associated with clade Ib, which seems to be milder than clade Ia

General advice to travelers (including children)*

- Avoid close contact with people with signs and symptoms of mpox, including those with skin or genital lesions
- Avoid contact with contaminated materials (e.g., clothing, bedding, utensils, toothbrushes) used by people who have mpox
- Be aware that in countries that are not endemic for mpox, mpox among adults is spread predominantly via sexual contact (regardless of sexual orientation and gender identity) †

*<https://wwwnc.cdc.gov/travel/notices/level2/clade-1-mpox-central-eastern-africa>

†<https://www.who.int/publications/m/item/multi-country-outbreak-of-mpox--external-situation-report-35--12-august-2024>

Summary

- Clade II
 - Mpox vaccinations not recommended for people who recovered from mpox
 - Booster dose not recommended for people vaccinated during 2022
 - Booster doses recommended for certain laboratorians because virus to which they are exposed might be up to 1000x more concentrated
 - Healthcare personnel not routinely recommended to receive mpox vaccination
- Clade I
 - JYNNEOS expected to be effective against both clades (and sub-clades)
 - Vaccination (in addition to counseling) recommended for travelers who anticipate certain sexual behaviors during travel
 - Risk to children during travel expected to be low but counseling about prevention strategies should be provided

Thank you

poxvirus@cdc.gov

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.

National Center for Emerging and Zoonotic Infectious Diseases
Division of High-Consequence Pathogens and Pathology

