



## Clinical guidance and next steps

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# Guidance about vaccination before exposures to mpox

- Similar to what has previously been presented to ACIP
- Specific to pre-exposure vaccination
- Specific to the population at risk for mpox\*

\*Interim recommendation to be revisited in 2-3 years

† Dose 2 administered 28 days after dose 1

§Persons at risk:

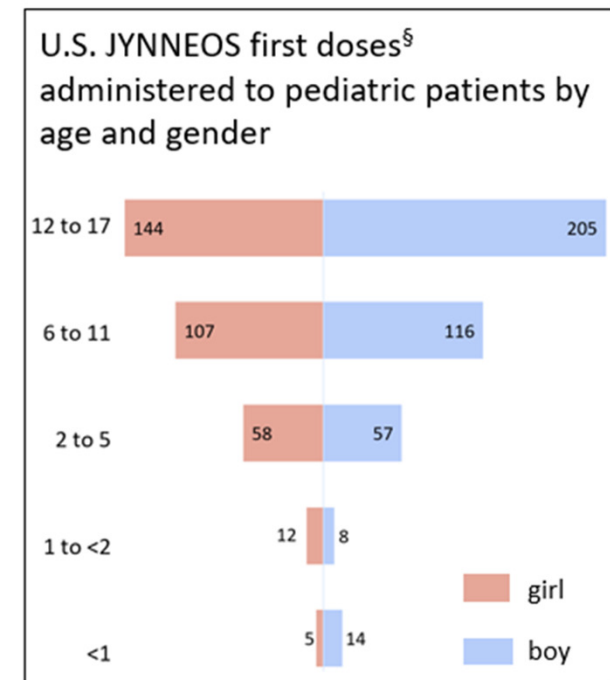
- Gay, bisexual, and other men who have sex with men, transgender or nonbinary people who in the past 6 months have had one of the following:
  - A new diagnosis of  $\geq 1$  sexually transmitted disease
  - More than one sex partner
  - Sex at a commercial sex venue
  - Sex in association with a large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

## Persons <18 years of age at risk for mpox

- JYNNEOS is not licensed for persons <18 years of age
- No pre-licensure studies in this population; however, no safety signals identified during the current outbreak
- NIH clinical trial in progress: Safety and immunogenicity of JYNNEOS in persons aged 12-17 years

- Adolescents at risk for mpox\* may receive the JYNNEOS vaccine before an exposure

\*See slide 2 for description of population at risk for mpox



<sup>§</sup> Fewer children received 2 doses (compared to 1 dose); CDC unpublished data (does not include data from one state)

# Pregnant or breastfeeding persons


- Pregnancy
  - Available human data insufficient to determine vaccine associated risks
  - However, animal models including in rats have shown no evidence of harm to the developing fetus
  - No adverse events reported via vaccine safety surveillance systems
- Safety in breastfeeding persons
  - Has not been evaluated
  - No adverse events reported via vaccine safety surveillance systems
- JYNNEOS is not contraindicated in pregnancy or while breastfeeding
- Pregnant or breastfeeding persons at risk for mpox\* may receive the JYNNEOS vaccine before an exposure

\*See slide 2 for description of population at risk for mpox

## Healthcare personnel

- Healthcare-associated mpox infections have been rare, typically associated with sharps injuries or exposure in the absence of personal protective equipment
- Healthcare personnel at risk for mpox because of the risk factors described (e.g., MSM with more than one sexual partner) should be vaccinated; however, this recommendation is not because of occupational risk
- JYNNEOS is not recommended as a routine vaccination for healthcare personnel unless sexual risk factors are present

\*See slide 2 for description of population at risk for mpox



# Myopericarditis

- Known risk after ACAM2000, a different orthopoxvirus vaccine; mechanism unknown so theoretical risk with JYNNEOS has not been ruled out
- Known risk after COVID-19 vaccines, particularly in adolescent and young adult males
- CDC websites for COVID-19 and mpox vaccines provide interim guidance for coadministration



## CDC guidance for coadministration of JYNNEOS with COVID-19 vaccines

- There is no required minimum interval between receiving any COVID-19 vaccine and JYNNEOS vaccine (e.g., for mpox prevention), regardless of which vaccine is administered first
- People, particularly adolescent and young adult males, who are recommended to receive both vaccines might consider waiting 4 weeks between vaccines. This is because of the observed risk for myocarditis and pericarditis after receipt of ACAM2000 orthopoxvirus vaccine and COVID-19 vaccines and the hypothetical risk for myocarditis and pericarditis after JYNNEOS vaccine. However, if a patient's risk for mpox or severe disease due to COVID-19 is increased, administration of JYNNEOS and COVID-19 vaccines should not be delayed

# Clinical guidance when JYNNEOS and immunoglobulin products are temporally administered

- Most immunoglobulin products: No precautions are necessary if JYNNEOS is administered in close temporal proximity to Intravenous immunoglobulin (IVIG)
- Vaccinia immune globulin intravenous (VIGIV)
  - Could interfere with immune response to JYNNEOS
    - Ideally, administration of JYNNEOS should be delayed if VIGIV was recently administered
    - The duration for which it should be delayed is unknown; public health consultation should be obtained for case specific guidance
  - Unlikely that VIGIV would be administered in close proximity to JYNNEOS




## Contraindications and precautions

- JYNNEOS was licensed\* for prevention of smallpox in addition to prevention of mpox
- Because smallpox is nearly always life-threatening, there are no absolute contraindications; however, for mpox, considerations may be different
- Consistent with contraindications in ACIP routine schedules, WG proposed
  - JYNNEOS contraindicated in patients with a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component
  - Precautions: Moderate or severe acute illness, with or without fever

\*<https://www.fda.gov/media/131078/download>

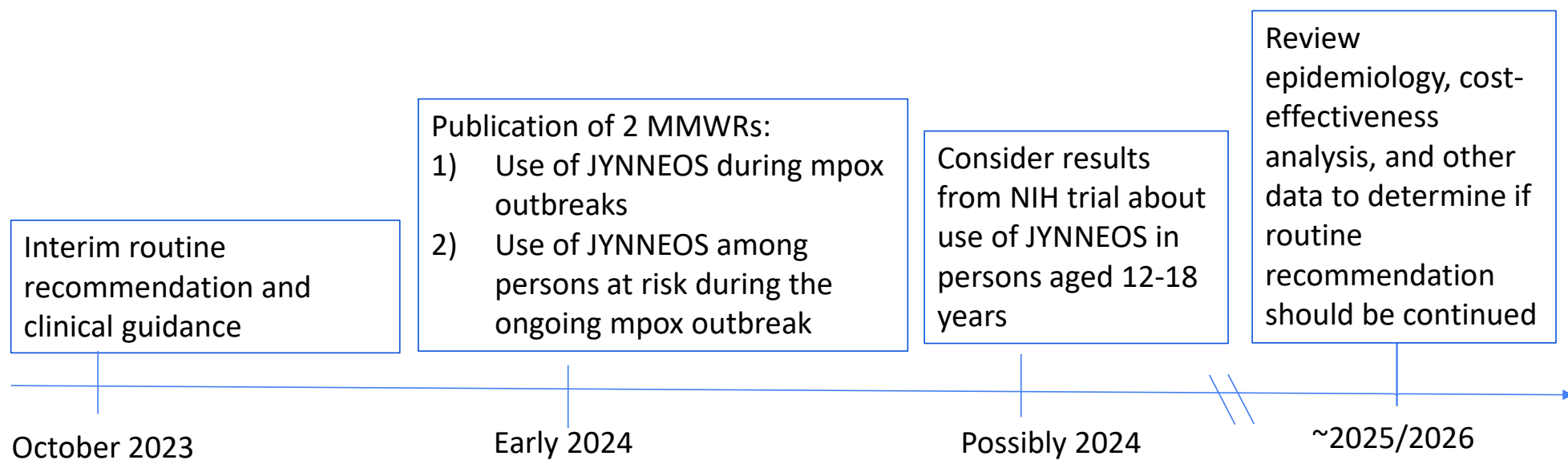


## Other administration guidance

- Completion of the 2-dose series should be encouraged
  - As much as possible, the 2<sup>nd</sup> dose of JYNNEOS should be administered ~28 days after the first dose
  - Unintentional delays in receiving the 2<sup>nd</sup> dose does not require restarting the series; the second dose should be administered as soon as possible even if >1 year has elapsed
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**Next steps**

# Tentative timeline for ACIP discussions and votes\*



\*February 2023 and June 2023 votes do not impact existing recommendations for the current mpox outbreak.

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

## Proposed recommendation is interim recommendation

- If passed, recommendations will be revisited in 2-3 years
- Epidemiology at the time may inform decision about continuing routine vaccinations
- Vaccine may be commercialized by that time
- Cost-effectiveness analysis will be performed

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# Questions?

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

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