National Center for Emerging and Zoonotic Infectious Diseases

Clinical guidance and next steps

Agam Rao, MD

CAPT, US Public Health Service

Poxvirus and Rabies Branch

Centers for Disease Control and Prevention

Advisory Committee on Immunization Practices

October 25, 2023

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*

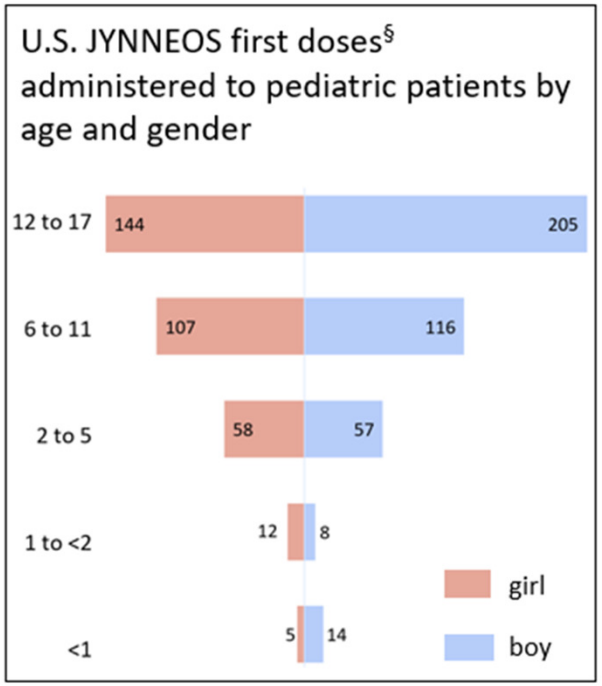
*Interim recommendation to be revisited in 2-3 years
† Dose 2 administered 28 days after dose 1
§Persons at risk:

- 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 ≥ 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



§ Fewer children received 2 doses (compared to 1 dose); CDC unpublished data (does not include data from one state)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

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html

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

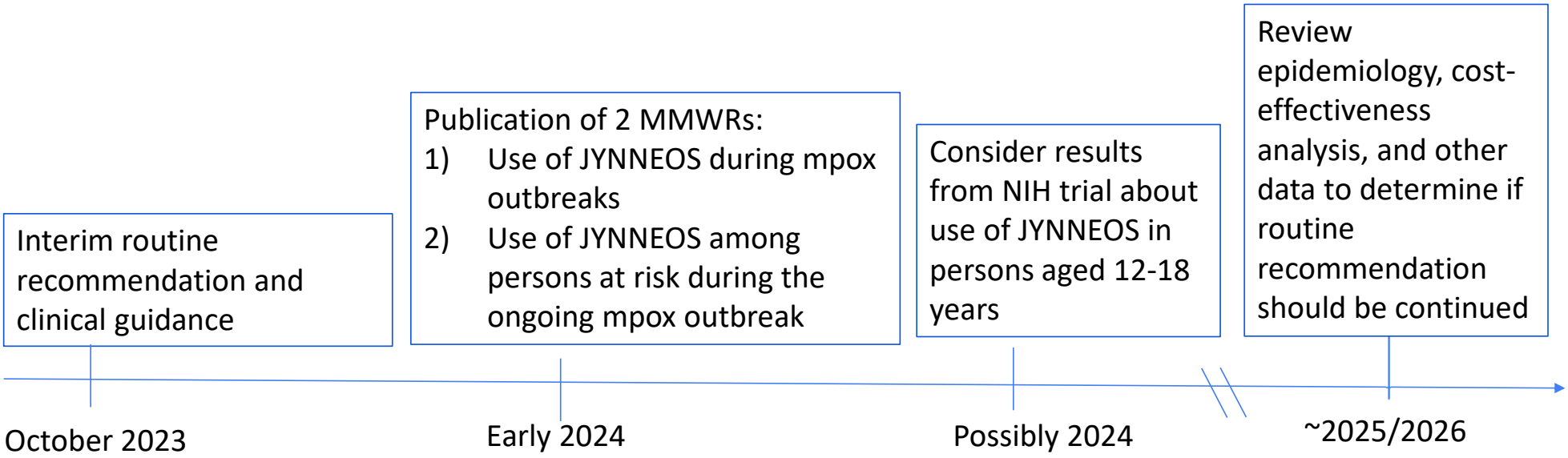
*https://www.fda.gov/media/131078/download

Other administration guidance

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

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

Acknowledgements

- ACIP Work Group
- Howard Minkoff
- Jane Zucker
- Jim Campbell
- Sathesh Panayampalli
- Alli Tuttle
- Jonathan Duffy
- Rosalind Carter
- Neil Murthy
- Patricia Wodi
- Mark Russi
- Marie de Perio
- Jason Zucker
- John Brooks
- David Kuhar
- Evelyn Twentyman
- Sara Oliver

Questions?

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