



# Mpox Vaccine Work Group: Introduction

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Chair, ACIP Mpox Work Group**

**ACIP Meeting**

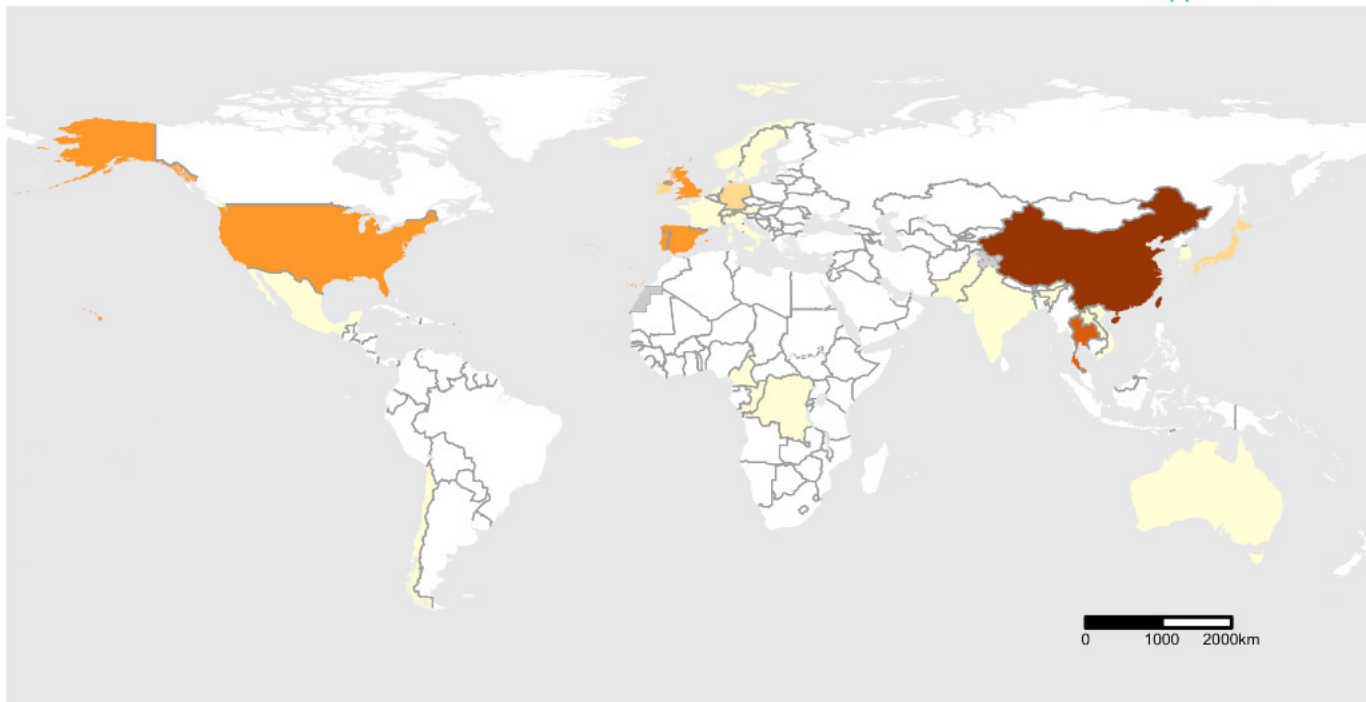
**October 25, 2023**

## Global mpox outbreak, 2022

- First case in this outbreak identified in the United Kingdom in May 2022
- Primarily affecting gay, bisexual, and other men who have sex with men (MSM)
- Associated with person-to-person spread via close skin-to-skin contact including sex
- Deaths have occurred, primarily among persons with severe immunocompromise from advanced HIV
- U.S. case counts and deaths comprising 1/3 of cases and deaths
  - >30,800 cases
  - 54 deaths

# Current global cases reported to WHO, September, 2023

Confirmed cases of mpox, September 2023



- Not applicable
- No data

### Confirmed cases

- 0
- 1-9
- 10-29
- 30-99
- 100-199
- 200+

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Data Source: World Health Organization  
Map Production: WHO Health Emergencies Programme  
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[https://worldhealthorg.shinyapps.io/mpx\\_global/](https://worldhealthorg.shinyapps.io/mpx_global/)

# JYNNEOS

- Comprised of replication-deficient vaccinia virus
- Administered subcutaneously\* via 2 vaccine doses, 28 days apart
- Effectiveness assessed by comparing immunologic response to that for ACAM2000
- Licensed for prevention of both smallpox and mpox
- Is recommended for persons with HIV and other immunocompromising conditions
- Licensed for persons  $\geq 18$  years of age; an NIH trial is underway to evaluate safety and immunogenicity for persons 12-17 years of age

\*During the 2022 mpox outbreak, it was also administered intradermally because of limited vaccine availability; it is currently available in enough supply




# Outbreak recommendation: February and June ACIP meetings

- Vote: ACIP recommends the 2-dose\* JYNNEOS vaccine series for persons aged 18 years and older at risk of mpox during an mpox outbreak†

\*Dose 2 administered one month after dose 1

†Public health authorities determine whether there is an mpox outbreak; a single case may be considered an mpox outbreak at the discretion of public health authorities. Other circumstances in which a public health response may be indicated including ongoing risk of introduction of mpox into a community due to disease activity in another geographic area

- Outbreak recommendations intended for any U.S. mpox outbreak, regardless of whether associated with male-to-male sexual contact
  - Clinical guidance, including about use of vaccine in children during outbreaks discussed
- 

## National mpox vaccination strategy for pre-exposure vaccination during current outbreak\*

### Vaccination before exposure to mpox virus

- Gay, bisexual, and other MSM, transgender or nonbinary people (including adolescents who fall into the aforementioned categories) who in the past 6 months have had:
  - New diagnosis of  $\geq 1$  sexually transmitted disease
  - More than one sex partner
- People with the following in the last 6 months:
  - Sex at commercial sex venue
  - Sex in association with large public event in geographic area where mpox transmission is occurring
- Sexual partners of people with the above risks
- People who anticipate experiencing above risks
- People with HIV or other causes of immunosuppression who have had recent or anticipate potential mpox exposure

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

# Elimination of human-to-human transmission

- WHO strategy in development; additional resources and data needed
- Immunization may be one component of the strategy
- Elimination is a complex issue not addressed by WG; however, a recommendation that persons at-risk for mpox during the ongoing outbreak receive the vaccines if they have not already, may support any upcoming WHO strategy

# Recommendation that will be proposed during today's meeting

ACIP recommends vaccination\* with the 2-dose<sup>†</sup> JYNNEOS vaccine series for persons aged 18 years and older at risk for mpox<sup>§</sup>?

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

<sup>†</sup> Dose 2 administered 28 days after dose 1

<sup>§</sup> 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



## Potential implications of interim routine recommendation

- Increase vaccine coverage and prevent or minimize outbreaks
- Remove some stigma and facilitate 1:1 consultation with clinician during appointments

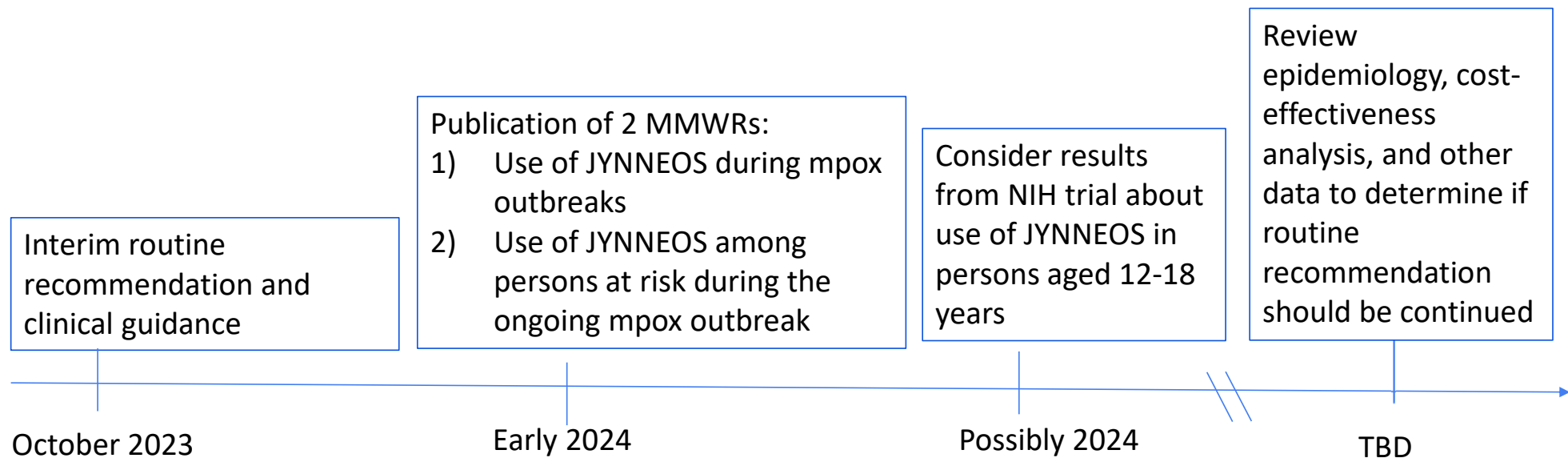


## Potential commercialization of JYNNEOS

- Product sponsor (Bavarian Nordic) has indicated they will attempt to commercialize the vaccine if it is on a routine schedule
- This will transition vaccine from U.S. government stockpiles (which were intended for smallpox preparedness) to the commercial sector



# Tentative timeline for ACIP discussions and votes\*



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

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

# Proposed recommendation

ACIP recommends vaccination\* with the 2-dose<sup>†</sup> JYNNEOS vaccine series for persons aged 18 years and older at risk for mpox<sup>§</sup>?

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

<sup>†</sup> Dose 2 administered 28 days after dose 1

<sup>§</sup>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:
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  - 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

## Goal for today's meeting

- Updates from the ongoing outbreak
  - Epidemiology: Dr. Faisal Minhaj
  - Evidence to recommendations framework: Dr. Agam Rao
  - Clinical guidance and next steps: Dr. Agam Rao
- Vote
  - Mpox vote
  - Mpox Vaccines for Children vote

## **WG members**

### **ACIP Member**

*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*

*HRSA: Vikram Krishnasamy*

*AIM: Rob Schechter / Jane Zucker*

*APHL: Jafar Razeq*

*NIH: Janet Lathey / Kimberly Taylor*

*IHS: Matthew Clark*

*NACI: Nicole Forbes / Joshua Montroy*

*IDSA: Shireesha Dhanireddy / Rajesh Gandhi*

### **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*

# Clinician experts

## STIs, HIV, and mpox (adult and peds):

*Jason Zucker*

*Pablo Tebas*

*Vince Marconi*

*Kim Workowski*

*Bonnie Maldonado*

## Immunizations (including for special populations) and vaccine safety:

*Ruth Karron*

*Flor Munoz-Rivas*

*Kathy Edwards*

## Health equity, vaccination strategies including for smallpox:

*Joel Breman*

*Gerard Vong*

## Occupational Medicine and worker safety:

*Mark Russi*



# CDC contributors

## Mpox epi, lab, and vaccine experts

*Andrea McCollum*

*Christy Hutson*

*Sathesh Panayampalli*

## Infection control, worker safety:

*Marie de Perio*

*David Kuhar*

## Vaccine safety

*Jonathan Duffy*

*Michael McNeil*

## Regulatory Affairs

*Yon Yu*

## STIs and HIV

*Laura Bachmann*

*Leandro Mena*

*John Brooks*

*Alexa Oster*

## Drug Services

*Julian Jolly*

## Vaccine implementation

*Laura Daniel*

*James Lee*

## DoD Liaison to CDC

*Alan Lam*

## Work group lead

*Agam Rao*





# Thank you!

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.

