Mpxo Vaccine Work Group

Pablo Sanchez MD
The Ohio State University–Nationwide Children’s Hospital
Chair, ACIP Mpxo Work Group

ACIP Meeting
February 22, 2023
Mpxo – Historical Context

- Rare, sometimes life-threatening infection
- Endemic in parts of west and central Africa
- Caused by monkeypox virus (which is an orthopoxvirus)
  - Clade I (previously Congo Basin Clade)
  - Clade II (previously West African Clade)
- Can spread from infected animals to people and then person-to-person
  - Respiratory secretions
  - Skin-to-skin contact with infected bodily fluids (e.g., fluid from lesions)
  - Fomites (e.g., shared towels, clothing, and bedding)
Timeline of Notable Human Mpox Events*

1970
- First human case identified
- Rural settings

2003
US outbreak from pet prairie dogs (cohoused with infected small mammals from Ghana): 47 cases

2017
Outbreak in Nigeria involving 17 states: 138 cases

2018
Imported cases to UK and Israel: 3

2019
Imported cases to UK, Singapore: 2

2021
Imported human cases to UK and US: 3

2022
Multinational outbreak

*During 1970-2021, mpox was known to be endemic in 9 African countries: Cameroon, Central African Republic, Cote d’Ivoire, Democratic Republic of Congo, Gabon, Liberia, Nigeria, Republic of Congo, and Sierra Leone; during recent years, there has been a re-emergence of human cases after decades of no reported cases.
Person-to-person spread

- Historical outbreaks in Africa
  - Associated with close skin-to-skin contact and contact with fomites
  - Zoonotic exposure cause of most cases
  - Few secondary cases among close contacts (e.g., household contacts)

- US outbreaks
  - 2003: No secondary cases $\rightarrow$ no vaccinations offered
  - 2021: No secondary cases $\rightarrow$ ACAM2000 offered to some contacts*
  - 2022: Many secondary cases $\rightarrow$ >1 million doses of JYNNEOS administered

*ACAM2000 was offered through a CDC Investigational New Drug Protocol that allows for vaccination after mpox exposure. Only contacts with high-risk exposures were offered vaccine; none accepted.
2021 ACIP Orthopoxvirus Vaccine Vote

- Use of orthopoxvirus vaccine, JYNNEOS, (licensed in 2019) for pre-exposure vaccination of people at occupational risk for orthopoxvirus exposures
- 2-dose series, subcutaneous administration
- Recommendations published June 3, 2022*

*https://www.cdc.gov/mmwr/volumes/71/wr/mm7122e1.htm
Currently no ACIP recommendation for use of JYNNEOS during outbreaks
**Current U.S. national mpox vaccination strategy***

<table>
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<tr>
<th>Vaccination before exposure to mpox virus</th>
<th>Post-exposure prophylaxis</th>
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| - 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 |

| - People who are known contacts to someone with mpox and identified by public health authorities (for example, via case investigation, contact tracing, or risk exposure assessment)  
- People who are aware that a recent sex partner within the past 14 days was diagnosed with mpox  
- Gay, bisexual, or other MSM, and transgender or nonbinary people (including adolescents who fall into any of the aforementioned categories) who have had any of the following within the past 14 days: sex with multiple partners (or group sex); sex at commercial sex venue; or sex in association with an event, venue, or defined geographic area where mpox transmission is occurring |

*https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/overview.html*
U.S. strategy for vaccination with JYNNEOS during current outbreak

- Intradermal preferred but subcutaneous can be administered for persons aged ≥ 18 years
- Subcutaneous for persons aged <18 years*
- 2-dose series with second dose administered 1 month after first dose

*https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/overview.html
Tentative timeline for ACIP discussions and votes*

February 2023
Mpox outbreaks: Use of 2-dose JYNNEOS for persons aged ≥ 18 years

June 2023
Mpox outbreaks: Use of 2-dose JYNNEOS for persons aged <18 years
-Updates about vaccine effectiveness and safety

October 2023
Consider need for longer term vaccination strategy for 2-dose JYNNEOS

*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
Tentative timeline for ACIP discussions and votes*

Current US mpox vaccination strategy remains active: Populations at high risk should continue to be vaccinated §

February 2023

Mpx outbreaks: Use of 2-dose JYNNEOS for persons aged ≥ 18 years

June 2023

Mpx outbreaks: Use of 2-dose JYNNEOS for persons aged <18 years
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October 2023

Consider need for longer term vaccination strategy for 2-dose JYNNEOS

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§ https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/overview.html
Goal for today’s meeting

- Updates from the ongoing outbreak
  - Epidemiology: Sascha Ellington
  - Vaccine effectiveness: Anna Chard
  - Vaccine safety: Jonathan Duffy
  - Community engagement: Kevin Delaney
  - Equity and implementation: Rosalind Carter

- Discuss use of 2-dose JYNNEOS (subcutaneous) during mpox outbreaks
  - Evidence to recommendations (EtR) framework: Agam Rao
  - ACIP vote
Proposed wording for today’s 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 include ongoing risk of introduction of mpox into a community due to disease activity in another geographic area.
**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

AIM: Rob Schechter / Jane Zucker
APHL: Jafar Razeq
NIH: Janet Lathey / Kimberly Taylor
IHS: Matthew Clark
NACI: Nicole Forbes / Oliver Baclic
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
Jeanne Marrazzo
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

**Mpxo epi, lab, and vaccine experts**
- Brett Petersen
- Andrea McCollum
- Christy Hutson

**Laboratory Response Network:**
- Julie Villanueva

**Infection control, worker safety:**
- Marie de Perio
- David Kuhar

**Special populations (e.g., Persons experiencing homelessness)**
- Emily Mosites

**Vaccine safety**
- Michael McNeil
- Jonathan Duffy

**Regulatory Affairs**
- Yon Yu

**STIs and HIV**
- Laura Bachmann
- Leandro Mena
- John Brooks
- Alexa Oster

**Drug Services**
- Julian Jolly

**Vaccine implementation**
- Liz Velasquez
- James Lee

**DoD Liaison to CDC**
- Alan Lam

**Work group lead**
- Agam Rao