

Mpox Vaccine Work Group

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Chair, ACIP Mpox Work Group

ACIP Meeting June 23, 2023

Mpox outbreaks

- Before 2022, rare outside of Africa
- In Africa, have involved 2 clades:
 - Clade I (previously Congo Basin Clade)
 - Clade II (previously West African Clade)
- In United States, have involved Clade II
 - Clade IIa: 2003 U.S. outbreak associated with pet prairie dogs
 - Clade IIb: 2022/2023 global outbreak associated with male-to-male sexual contact
- Historically: Clade I believed to be associated with more severe disease than Clade II

Severe manifestations observed in severely immunocompromised persons during the 2022/2023 outbreak: Clade IIb



Carrubba S, Geevarghese A, Solli E et al. Novel severe oculocutaneous manifestations of human monkeypox virus infection and their historical analogues. Lancet Infect Dis. 2023 Jan 23:S1473-3099(22)00869-6.

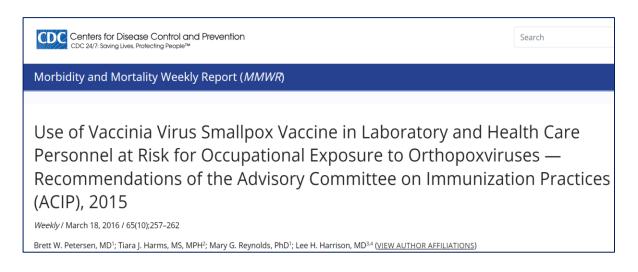


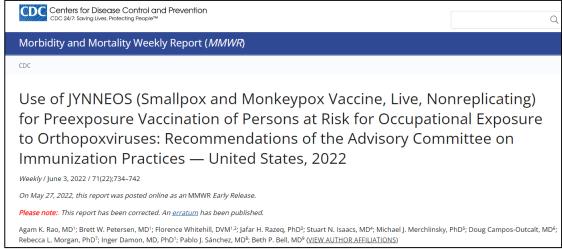
Menezes YR, Miranda AB. Severe disseminated clinical presentation of monkeypox virus infection in an immunosuppressed patient: first death report in Brazil. Rev Soc Bras Med Trop. 2022 Aug 29;55:e0392.

ACIP recommendations

- With global eradication of smallpox, routine vaccinations against orthopoxviruses were no longer needed
- Routine smallpox vaccinations stopped globally in 1980 (USA, 1972)
- ACIP recommendations for persons at occupational risk for orthopoxvirus infections since 1980
 - Largest proportion of people recommended to be vaccinated are research laboratorians who work with orthopoxviruses (including monkeypox virus [MPXV])
 - ACAM2000 and JYNNEOS are the vaccines recommended

Current ACIP recommendations for persons at risk for occupational exposure: ACAM2000 and JYNNEOS





- Since 2015, ACAM2000 recommended
- In November 2021, JYNNEOS recommended as alternative to ACAM2000

ACAM2000 compared to JYNNEOS

	ACAM2000	DAMMEOS		
Vaccine virus	Live, replication competent vaccinia virus	Live, replication deficient vaccinia		
Administration	Via multiple percutaneous puncture technique (single dose)	Subcutaneously* via 2 vaccine doses, 28 days apart		
Take	Inadvertent inoculation and autoinoculation can occur via vaccine site lesion	No risk of inadvertent inoculation and autoinoculation with vaccinia virus		

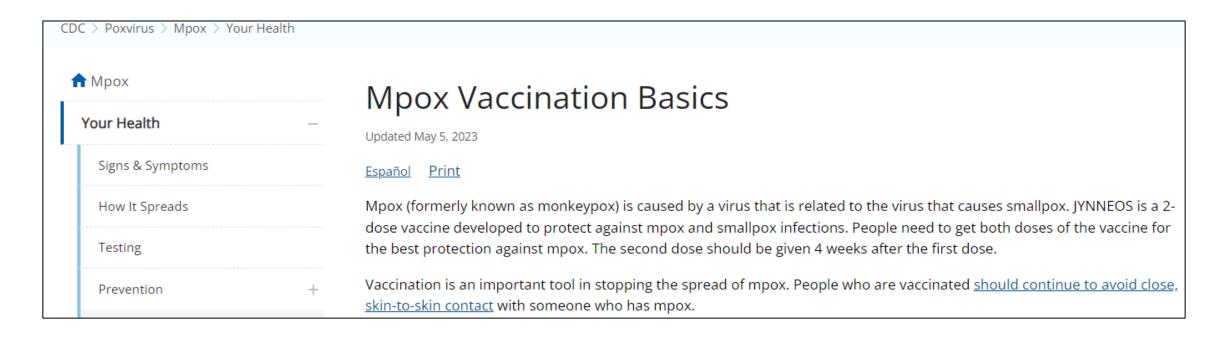
^{*}During the 2022/2023, intradermal was the preferred route of administration; vaccine effectiveness data indicates this route has been equally effective

Contraindications for ACAM2000 and JYNNEOS

Contraindications	ACAM2000 Primary Vaccinees	ACAM2000 Revaccinees	ACAM2000 Household Contacts*	JYNNEOS
History or presence of atopic dermatitis	X	X	X	
Other active exfoliative skin conditions	X	Χ	X	
Conditions c/w immunosuppression	X	X	X	
Pregnancy	Х	Х	X	
Aged <1 year	Х	Χ	Х	
Breastfeeding	Х	Х		
Serious vaccine component allergy	Х	Χ		X
Known underlying heart disease (e.g., coronary artery disease or cardiomyopathy)	X	X		
≥3 known major cardiac risk factořs	Х			

2022/2023 U.S. mpox outbreak: JYNNEOS recommended

- Fewer contraindications and adverse events with JYNNEOS
- Before this outbreak, no real-world experience with JYNNEOS



Short-term goal of the Work Group

- Currently no ACIP recommendation for use of JYNNEOS during mpox outbreaks
- Develop ACIP recommendations for use of JYNNEOS during mpox outbreaks*

^{*} 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.

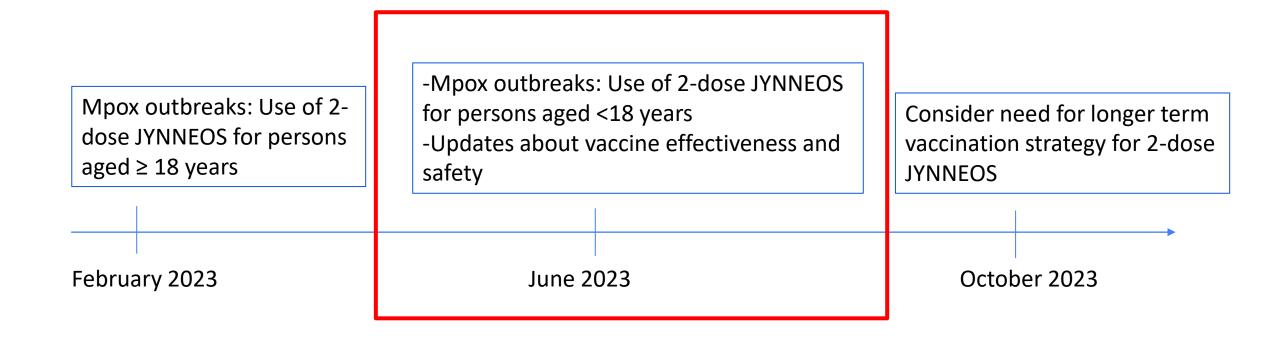
February 2023 ACIP meeting: Vote passed for use of JYNNEOS during outbreaks

ACIP recommends the 2-dose* JYNNEOS vaccine series for persons aged 18 years and older at risk of mpox during an mpox outbreaks

^{*}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.

Timeline that was proposed during February 2023*



^{*}These votes do not impact existing recommendations for the current mpox outbreak.

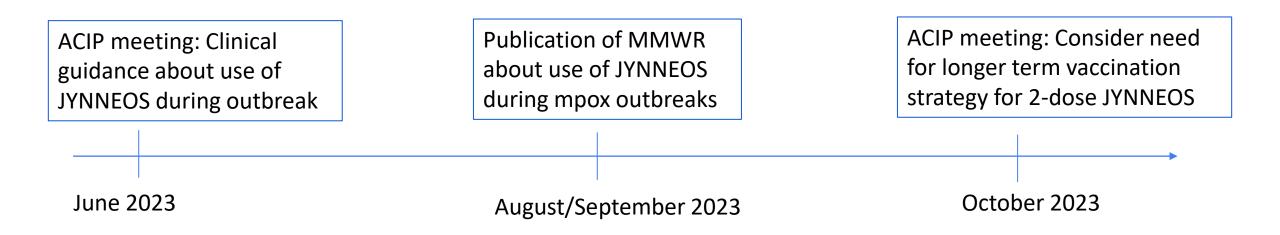
[§] https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/overview.html

Agenda for today's meeting

- Updates about epidemiology, vaccine safety, and vaccine effectiveness during the ongoing outbreak: Faisal Minhaj
- Clinical guidance about the use of 2-dose JYNNEOS (subcutaneous) series during mpox outbreaks: Agam Rao
- Considerations for long-term protection against mpox: Discussion in the context of the ongoing outbreak: Agam Rao

Tentative timeline for ACIP discussions and votes

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^{*}MMWR publication will not change the clinical guidance posted for the ongoing outbreak: https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/overview.html

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

<u>Immunizations (including for special populations) and vaccine safety:</u>

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

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

<u>Vaccine</u> implementation

Liz Velasquez 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

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.

