Centers for Disease Control and Prevention

Evidence to Recommendations Framework: Routine Vaccination with Jynneos for Adolescents at Risk of Mpox

Faisal Syed Minhaj, PharmD, MPH

Poxvirus and Rabies Branch

Centers for Disease Control and Prevention

Advisory Committee on Immunization Practices

April 15, 2025

EtR Question

Does ACIP recommend vaccination* with the 2-dose† JYNNEOS vaccine series for persons aged 12–17 years at risk for mpox§?

*Interim recommendation to be revisited in 2-3 years

† Dose 2 administered 28 days after dose 1

§Persons at risk:

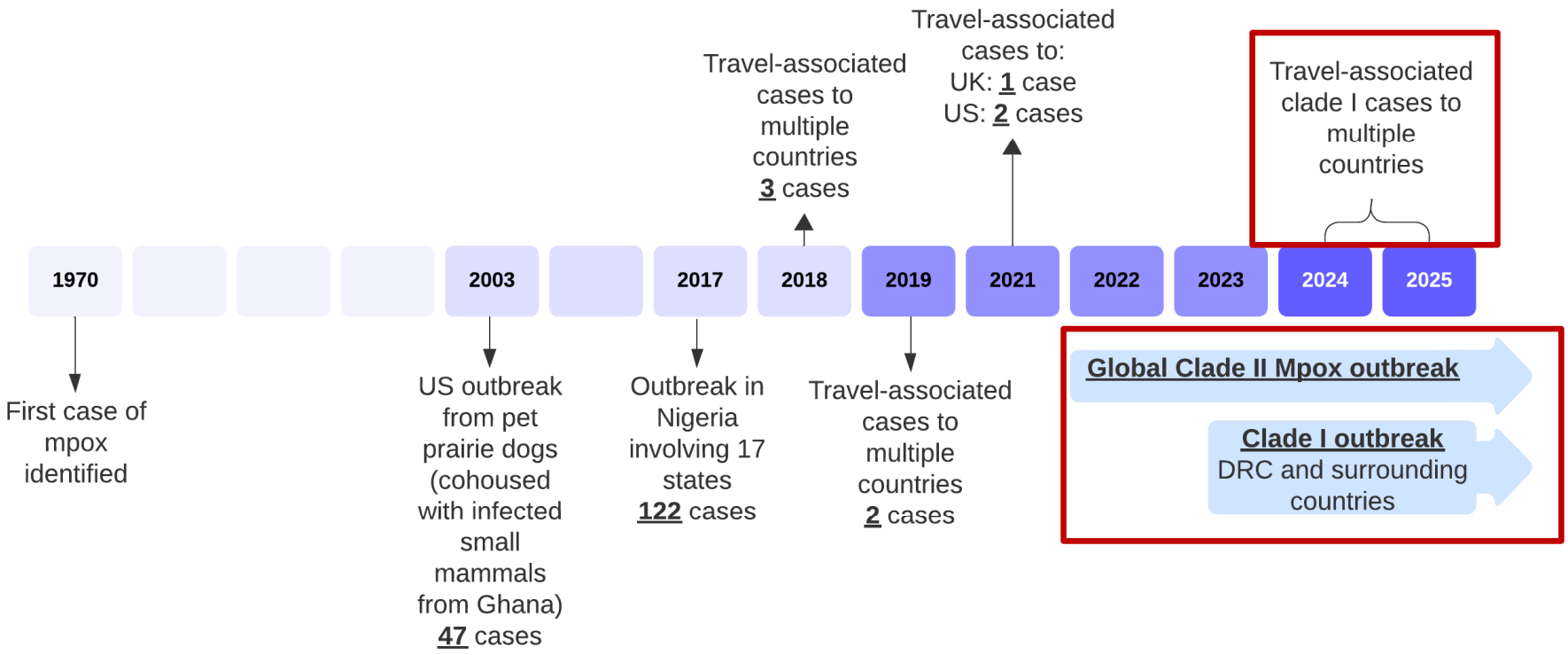
1. Gay, bisexual, and other men who have sex with men (MSM), or a person who has sex with MSM, who in the past 6 months have had one of the following:
    - A new diagnosis of ≥ 1 sexually transmitted disease
    - More than one sex partner
    - Sex at a commercial sex venue
    - Sex in association with a large public event in a geographic area where mpox transmission is occurring
2. Sexual partners of persons with the risks described in above
3. Persons who anticipate experiencing any of the above

Evidence to Recommendation Domains

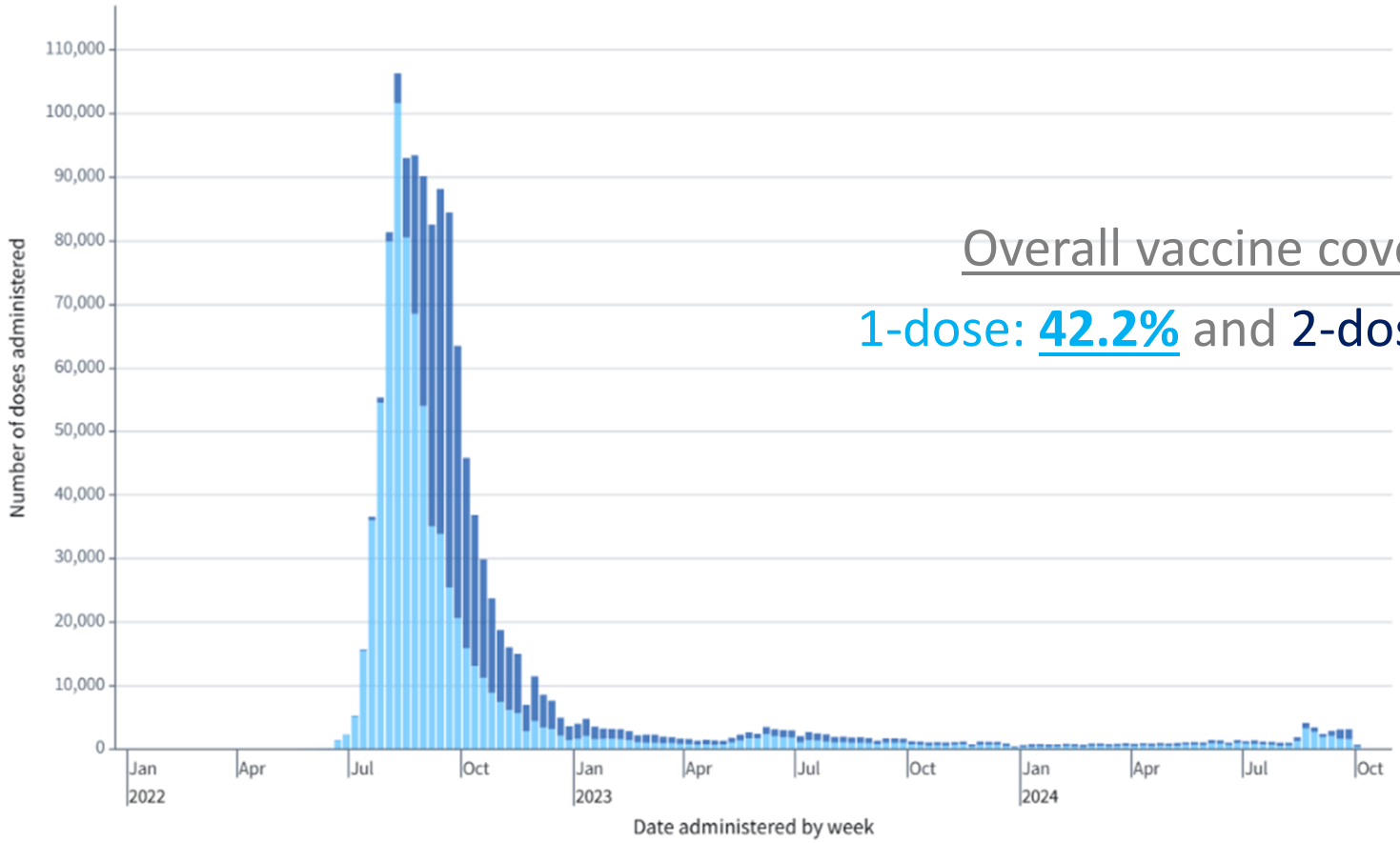
EtR Domain	Question(s)
Public Health Problem	• Is the problem of public health importance?
Benefits and Harms	• How substantial are the desirable anticipated effects? • How substantial are the undesirable anticipated effects? • Do the desirable effects outweigh the undesirable effects?
Values	• Does the target population feel the desirable effects are large relative to the undesirable effects? • Is there important uncertainty or variability in how much people value the main outcome?
Acceptability	• Is the intervention acceptable to key stakeholders?
Equity	• What would be the impact on health equity?
Feasibility	• Is the intervention feasible to implement?
Resource Use	• Is the intervention a reasonable and efficient allocation of resources?

EtR Domain: Public Health Problem

Mpox current situation



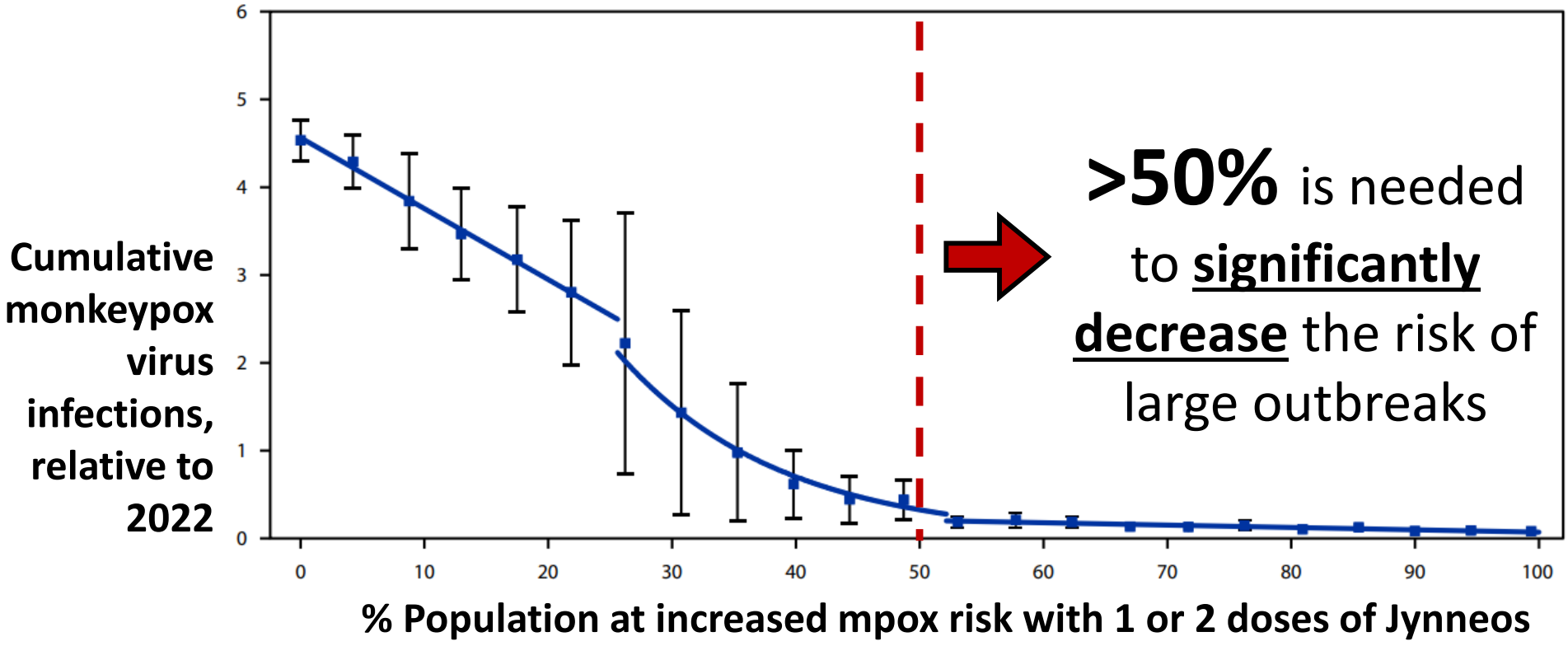
Jynneos vaccine coverage in the United States among people at risk for mpox – June 2022 through September 2024



Overall vaccine coverage

1-dose: **42.2%** and 2-dose: **26.2 %**

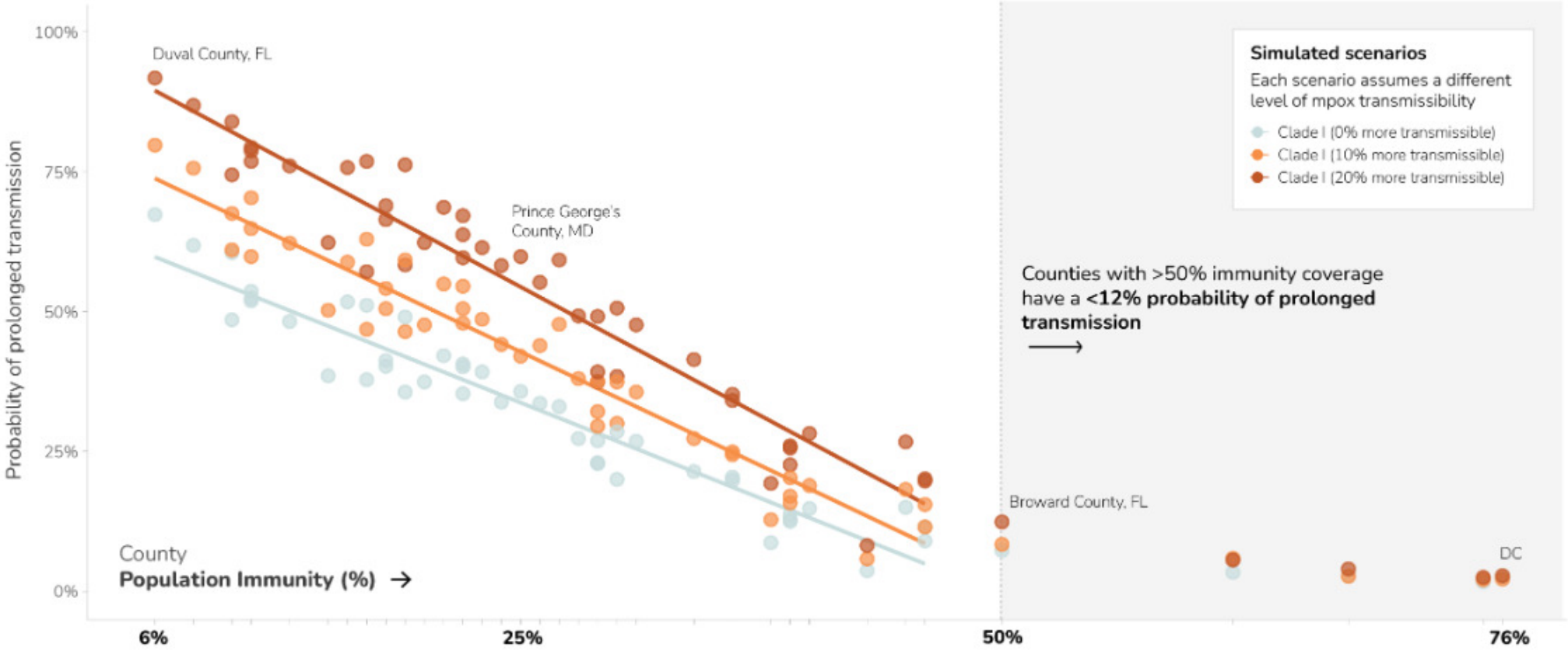
Cumulative *Monkeypox virus* infections relative to 2022, by immunity level — United States, 2023



Pollock ED. MMWR Morb Mortal Wkly Rep 2023;72:568–573.

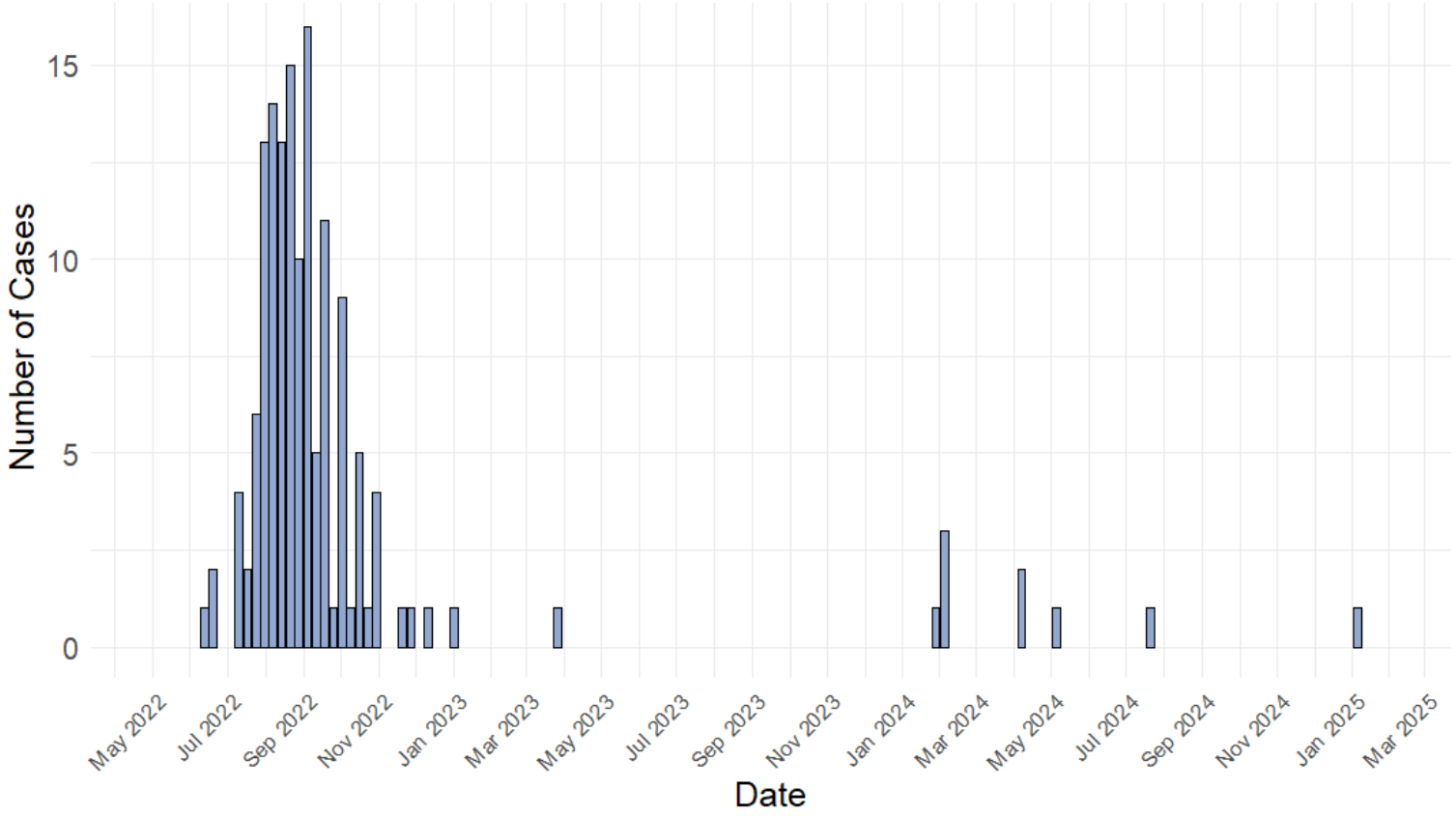
Probability of prolonged mpox transmission among MSM in U.S. counties

After one year, following introduction of five infectious individuals with high levels of sexual activity



https://www.cdc.gov/cfa-modeling-and-forecasting/mpox-gbmsm-technical-brief/nov24-update/

U.S. mpox case trends in adolescents and children, May 2022 through March 2025



Age group	Case Count
12-17	92
6-11	17
1-5	23
<1	15
Total	**147**

Are outbreaks of mpox of public health importance?

No Probably no Uncertain Probably Yes Yes

Varies

EtR Domain: Benefits and Harms

Adolescent safety and immunogenicity study summary

- Adolescent arm met pre-specified criteria for non-inferiority
  - GMT ratio of adolescents to adults was 1.60 (CI 1.32, 1.95)
- Vaccine was safe and well tolerated in adolescents
  - Solicited systemic and local AEs were similar between adolescents and adults
    - Systemic: 74% (CI 69, 79) vs 73% (CI 66, 79)
    - Local: 88% (CI 84, 91) vs 91% (CI 87,95)
  - Unsolicited related AEs: mainly injection site related
  - Dizziness in adolescents is common with vaccine administration in this age group and is not likely to represent a safety concern

Adverse events among individuals <18 years of age

- **Vaccine adverse event reporting system (VAERS)[1]**
  - At least 1,245 vaccinees nationwide
  - One report of syncope
  - Three reports of unspecified mild local and systemic reactions
- **VSD[2]**
  - 88 vaccinees
  - No adverse events of special interest observed
- **V-safe[1]**
  - No participants were <18 years of age
- **EIND[3]**
  - 57 vaccinees
  - 21% reported local or systemic reactions. No serious adverse events were reported

1) https://pubmed.ncbi.nlm.nih.gov/38647241/ 2) https://pubmed.ncbi.nlm.nih.gov/39565485/ 3) https://pubmed.ncbi.nlm.nih.gov/36480476/

How substantial are the *desirable* anticipated effects

Minimal Small Moderate Large

Don’t Know

Varies

How substantial are the *undesirable* anticipated effects

Minimal Small Moderate Large

Don’t Know

Varies

Do the desirable effects outweigh the undesirable effects?

Favors Intervention

Favors Both

Favors Comparison

Favors Neither

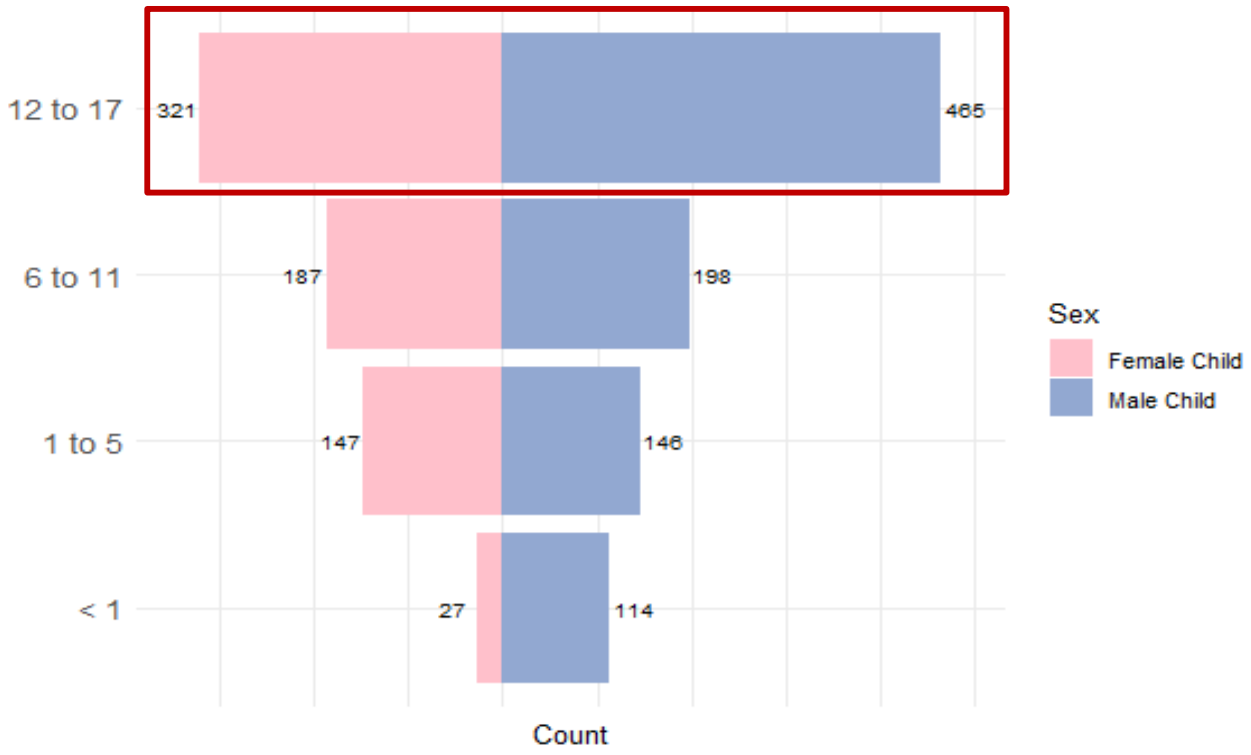
Unclear

EtR Domain: Values

Values Considerations

- NIH rapidly completed trial recruitment
- Participants were supportive in participating to help friends
- Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) youth advisors were surveyed and 12/13 respondents were supportive of vaccination
- When an outbreak occurred (i.e., 2022 global outbreak), pediatric close contacts were vaccinated

JYNNEOS first doses administered to children 17 years and younger by sex May 2022 – September 2024



Age group	Total first doses
12-17	798
6-11	391
1-5	293
<1	150
Total	**1,632**

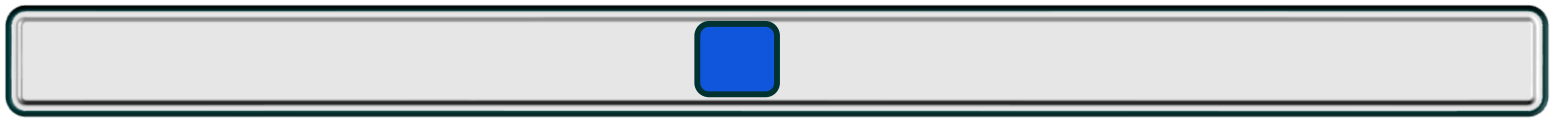
Persons with no age data available were removed from the analysis

Does the target population feel that the desirable effects are large relative to the undesirable effects?

No Probably no Uncertain Probably Yes Yes

Varies

Is there important uncertainty about or variability in how much people value the main outcomes?



Important uncertainty or variability

Possibly important uncertainty or variability

Probably no important uncertainty or variability

No important uncertainty or variability

No known undesirable outcomes

EtR Domain: Acceptability

Summary of Acceptability data

- Mothers from the survey do not view their children at risk for mpox.
  - However, the intent to vaccinate is higher than expected.
- Vaccines were primarily given to adolescents both through public health and STI clinics.
- Among 21 surveyed ATN providers who provide care for at-risk adolescents:
  - Over half already offer the mpox vaccine.
  - 95% would recommend mpox vaccines for eligible patients and do not have concerns about recommending the vaccine.
  - Majority expressed challenges associated with offering the vaccine; most common concern was financial cost to the clinic.

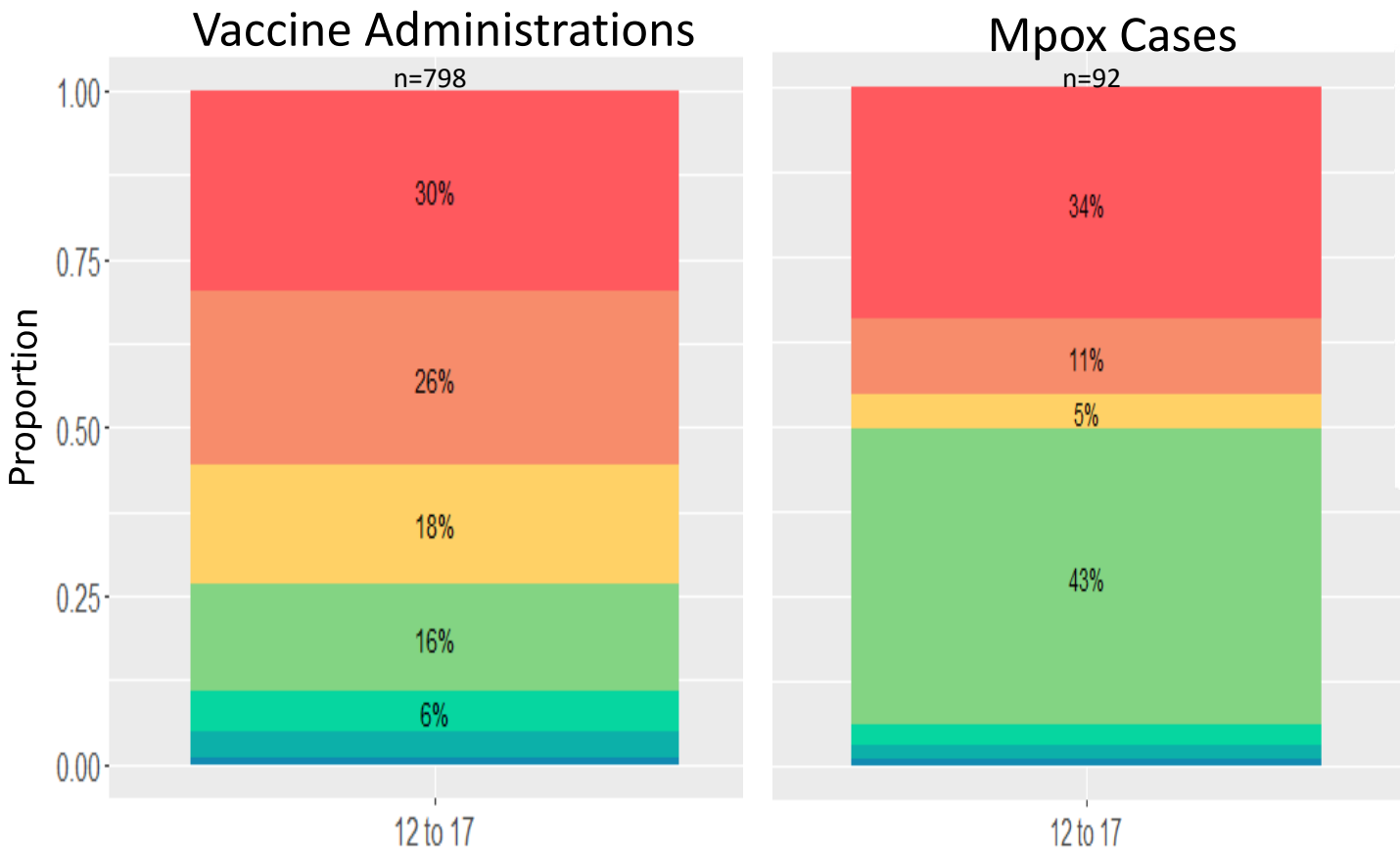
Is the intervention acceptable to key stakeholders?

No Probably no Uncertain Probably Yes Yes

Varies

EtR Domain: Health Equity

Vaccine administrations* and cases in adolescents by race and ethnicity, May 2022 – March 2025



Race and Ethnicity

- Hispanic or Latino
- White, non-Hispanic
- Unknown, non-Hispanic+
- Black, non-Hispanic
- Asian, non-Hispanic
- Other, non-Hispanic
- American Indian/Alaska Native, non-Hispanic
- Native Hawaiian/Other Pacific Islander, non-Hispanic

*Vaccine administration through September 2024, Case data through March 2025

+Includes 3 mpox cases indicating Multiple races. Multiple races was not reported for vaccine administration data.

If Hispanic or Latino was indicated for ethnicity, Race/ethnicity is indicated as Hispanic or Latino; if Hispanic or Latino ethnicity was not indicated, Race/ethnicity is indicated as Race

Health Equity

- No groups or settings were disadvantaged by recommendation for JYNNEOS use during mpox outbreaks.
- Immunogenicity is the same for immunocompetent persons 12-17 years.
- Implementation of vaccine should assure equitable access.
- Endorsement by ACIP could facilitate broad acceptance of recommendation (e.g., insurance, health departments, pharmacies).

What would be the impact on health equity?

Reduced | Probably Reduced | Probably no impact | Probably Increased | Increased

☐ Varies ☐ Don't know

EtR Domain: Feasibility

Feasibility Considerations

- Wide range of vaccinators can administer vaccine (pediatricians, pharmacists, public health nurses)
- Wide range of potential facilities: public health, STI clinic, adolescent health clinic, pediatrician offices
- Same Immunization Information Systems (IIS) requirements and reporting infrastructure as other vaccines
- Limitations to access
  - Poor access in rural communities
  - Cost of vaccine and 10 vial minimum ordering quantity could hinder practices stocking vaccine
  - Pediatricians may defer to STI/adolescent clinics

Feasibility Considerations

- Two doses, 28 days apart requires follow up and reminders
- JYNNEOS, once thawed/refrigerated, is good for either 4 or 8 weeks, allowing time to schedule a second dose.
- Frozen storage is ~18 months

Is the intervention feasible to implement?

No Probably no Uncertain Probably Yes Yes

Varies

EtR Domain: Resource Use

Resource Use

- JYNNEOS is commercially available
  - Similar mechanisms for billing/reimbursement
    - Medicaid/Medicare/317 funding/VFC
- Generally, vaccines are a good use of resources
- Cost-effectiveness of vaccination in adolescents is uncertain

Is the intervention a reasonable and efficient allocation of resources?

No | Probably no | Uncertain | Probably Yes | Yes

Varies

Balance of Consequences

Summary of Work Group Interpretation of EtR Domains

EtR Domain	Work Group Interpretation
Public Health Problem	Yes
Benefits and Harms	
Benefits	Large
Harms	Small
Benefit>Harm?	Favors intervention
Values	
Desirable>Undesirable?	Probably yes
Uncertainty?	Possibly important OR probably no important uncertainty or variability
Acceptability	Probably yes
Equity	Probably increased
Feasibility	Probably yes
Resource Use	Probably yes

Balance of consequences

Undesirable consequences *clearly outweigh* desirable consequences in most settings	Undesirable consequences *probably outweigh* desirable consequences in most settings	The balance between the desirable and undesirable consequences is *closely balanced or uncertain*	Desirable consequences *probably outweigh* undesirable consequences in most settings	Desirable consequences *clearly outweigh* undesirable consequences in most settings	There is insufficient evidence to determine the balance of consequences

Proposed Recommendation 2

ACIP recommends vaccination* with the 2-dose† JYNNEOS vaccine series for persons aged 12–17 years at risk for mpox§?

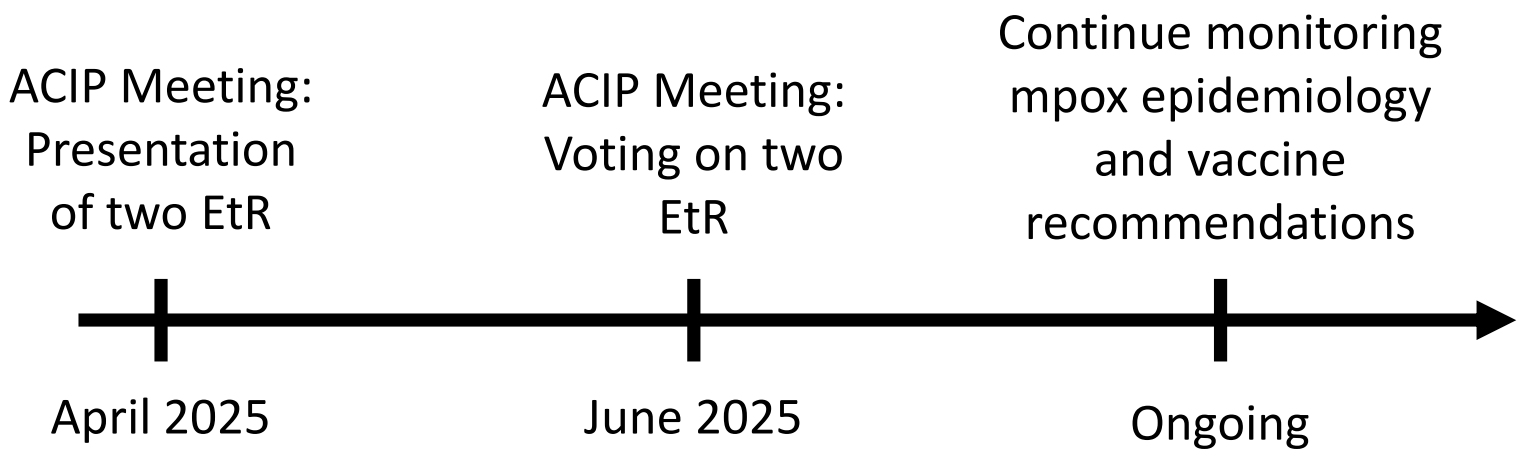
*Interim recommendation to be revisited in 2-3 years

† Dose 2 administered 28 days after dose 1

§Persons at risk:

1. Gay, bisexual, and other men who have sex with men (MSM), or a person who has sex with MSM 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
2. Sexual partners of persons with the risks described in above
3. Persons who anticipate experiencing any of the above

Tentative timeline for ACIP discussions and votes



Thank you

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