



Selected Updates from the June 2023 ACIP Meeting

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June 2023 ACIP Meeting Agenda

- Respiratory Syncytial Virus (RSV) Vaccines - Adult (Vote)
- Polio Vaccines (Vote)
- Influenza Vaccines (Vote)
- Pneumococcal Vaccines (Vote)
- Dengue Vaccines
- Chikungunya Vaccine
- RSV Vaccines - Pediatric/Maternal Vaccines
- Mpox Vaccines
- Meningococcal Vaccines
- Vaccine Safety Informational Session
- COVID-19 Vaccines

RSV Vaccines – Older Adults (VOTE)

Work Group interpretation (part 1)

- RSV vaccination has the potential to prevent considerable morbidity from RSV disease among older adults, particularly in those with chronic medical conditions and those who are frail (e.g., long-term care facility residents)
- Pfizer's bivalent RSVpreF and GSK's adjuvanted RSVPreF3 vaccines both have demonstrated significant efficacy against lower respiratory tract illness caused by RSV among older adults over at least two seasons
 - Trials were underpowered to show efficacy in the oldest adults and in adults who are frail
 - Trials were underpowered to show efficacy against RSV hospitalization
 - Efficacy against symptomatic illness may indicate efficacy against more severe disease

Work Group interpretation (part 2)

- Cases of inflammatory neurologic events have been reported within 42 days after vaccination with each RSV vaccine
- Clinical trials were not sufficiently powered to determine whether the small number of cases occurred due to random chance
- Whether there is an increased risk of GBS or other inflammatory neurologic events from RSV vaccination is not known at this time
- Post-licensure surveillance for both safety and vaccine effectiveness will be critical


Work group considerations: Resource Use

- RSV vaccination for older adults could be a cost-effective intervention
- There is substantial uncertainty in the net societal costs of an RSV vaccination program for older adults, driven by:
 - **Uncertainty in vaccine acquisition cost**
 - Current assumptions: \$200 Pfizer RSVpreF, \$270 GSK RSVPreF3
 - Uncertainty in incidence of RSV illness (e.g., hospitalization)
 - Uncertainty in duration of protection from RSV vaccination
 - Current assumption: 2 RSV seasons
- Vaccination of older age groups would be more cost effective than vaccination of younger age groups

Final Recommendation Language

- Adults 60 years of age and older may receive a single dose of RSV vaccine using shared clinical decision making.

Clinical consideration: Shared clinical decision-making based on risk assessment among adults aged ≥ 60 years



For shared clinical decision-making recommendations there is no default.

The decision about whether or not to vaccinate an individual may be informed by:

- Best available evidence of who may benefit
- An individual's characteristics, values, and preferences
- Health care provider's clinical discretion
- Characteristics of the⁸ vaccine being considered

Polio Vaccines (VOTE)

Summary of Problem

- US remains at risk of poliovirus importations as long as there is ongoing transmission of poliovirus globally
- Data indicate that most US adults have serologic immunity to poliovirus types 1–3
- However, unvaccinated and incompletely vaccinated adults remain susceptible to paralytic polio if exposed to poliovirus

2000 Statement on IPV Vaccination for Adults

Questions that arose in 2022

- 2000 statement focused on adults at **increased risk of poliovirus exposure**
- Uncertainty about how to define increased risk in setting of circulating vaccine-derived poliovirus (cVDPV) in US
- Unclear guidance for **unvaccinated** adults who were **not** known to be at increased risk of exposure
- Uncertainty about **vaccinated** adults and when/if a booster was advised

Vote – Unvaccinated and Incompletely Vaccinated Adults

Adults (aged ≥ 18 years) who are known or suspected to be unvaccinated or incompletely vaccinated against polio should complete a primary vaccination series with IPV.

Important context to be included in clinical considerations:

In general, unless there are specific reasons to believe they were not vaccinated, most adults who were born and raised in the United States can assume they were vaccinated against polio as children. Polio vaccination has been part of the routine childhood immunization schedule for decades and is still part of the routine childhood immunization schedule. Adults who received any childhood vaccines almost certainly were vaccinated for polio.

Vote - Recommendation for Adult IPV Booster

Adults who have received a primary series of trivalent OPV (tOPV) or IPV in any combination and who are at increased risk of poliovirus exposure may receive another dose of IPV. Available data do not indicate the need for more than a single lifetime booster dose with IPV for adults.

Influenza Vaccines (VOTE)

Overview of Proposed Recommendations

- Vaccination of all persons aged ≥ 6 months who do not have contraindications continues to be recommended.
- Recommendations regarding timing of vaccination are unchanged from 2022-23.
 - For most persons who need only 1 dose of influenza vaccine for the season, vaccination should ideally be offered during September or October.
 - Vaccination should continue after October and throughout the influenza season as long as influenza viruses are circulating and unexpired vaccine is available.
 - Vaccination during July and August are not recommended for most groups.
 - Considerations for July and August vaccination are noted for adults, children, and pregnant persons.
- Changes include:
 - Updated U.S. influenza vaccine composition for 2023-24.
 - Proposed changes to the recommendations for vaccination for persons with egg allergy.

Current ACIP Recommendations¹

- Persons with a history of egg allergy of any severity should receive influenza vaccine.
- Any licensed, recommended influenza vaccine (i.e., any IIV4, RIV4, or LAIV4) that is otherwise appropriate can be used.
- For persons with previous reactions to egg involving symptoms other than urticaria:
 - *“If a vaccine other than cclIV4 or RIV4 is used, the selected vaccine should be administered in an inpatient or outpatient medical setting, including but not necessarily limited to hospitals, clinics, health departments, and physician offices. Vaccine administration should be supervised by a health care provider who is able to recognize and manage severe allergic reactions.”*
- No specific observation period recommended.

1. CDC/ACIP. MMWR Recomm Rep 2022;71(No. RR-1):1–28.

IIV4= quadrivalent inactivated influenza vaccine

LAIV4=quadrivalent live attenuated influenza vaccine

cclIV4=quadrivalent cell culture based inactivated influenza vaccine

RIV4=quadrivalent recombinant influenza vaccine

Influenza Vaccines and Egg Allergy: Other Guidance

- American Academy of Pediatrics
 - *“Children with egg allergy can receive any influenza vaccine without any additional precautions beyond those recommended for all vaccines.”*¹
 - Measures related to use of specific vaccines, observation periods, or restricting vaccination to specific medical settings not warranted and constitute a barrier to vaccination.²
 - Not necessary to inquire about or screen for egg allergy prior to influenza vaccination.²
- Joint Task Force, AAAAI/ACAAI
 - “No special precautions beyond those recommended for the administration of any vaccine to any patient are necessary for administration of influenza vaccine to egg allergic individuals.”³

1. [Recommendations for Prevention and Control of Influenza in Children, 2022–2023 | Pediatrics | American Academy of Pediatrics \(aap.org\).](#)

2. [AAP. Technical Report for the 2022-23 Recommendations for the Prevention and Control of Influenza in Children, 2022-23](#)

3. [Greenhawt M et al. Ann Allergy Asthma Immunol 2018;120:49-52.](#)

Question

- Does the available evidence concerning the safety of influenza vaccines in persons with a history of egg allergy favor routine vaccination without additional safety measures, regardless of severity of previous allergic reaction to egg?
 - Review focused on Harms (safety)—did not include review of effectiveness/efficacy data.

VOTE - Recommendations for Vaccination of Persons with Egg Allergy

- All persons ages ≥ 6 months with egg allergy should receive influenza vaccine. Any influenza vaccine (egg based or non-egg based) that is otherwise appropriate for the recipient's age and health status can be used.

Dengue Vaccines

Dengvaxia™ ACIP Recommendation June 2021



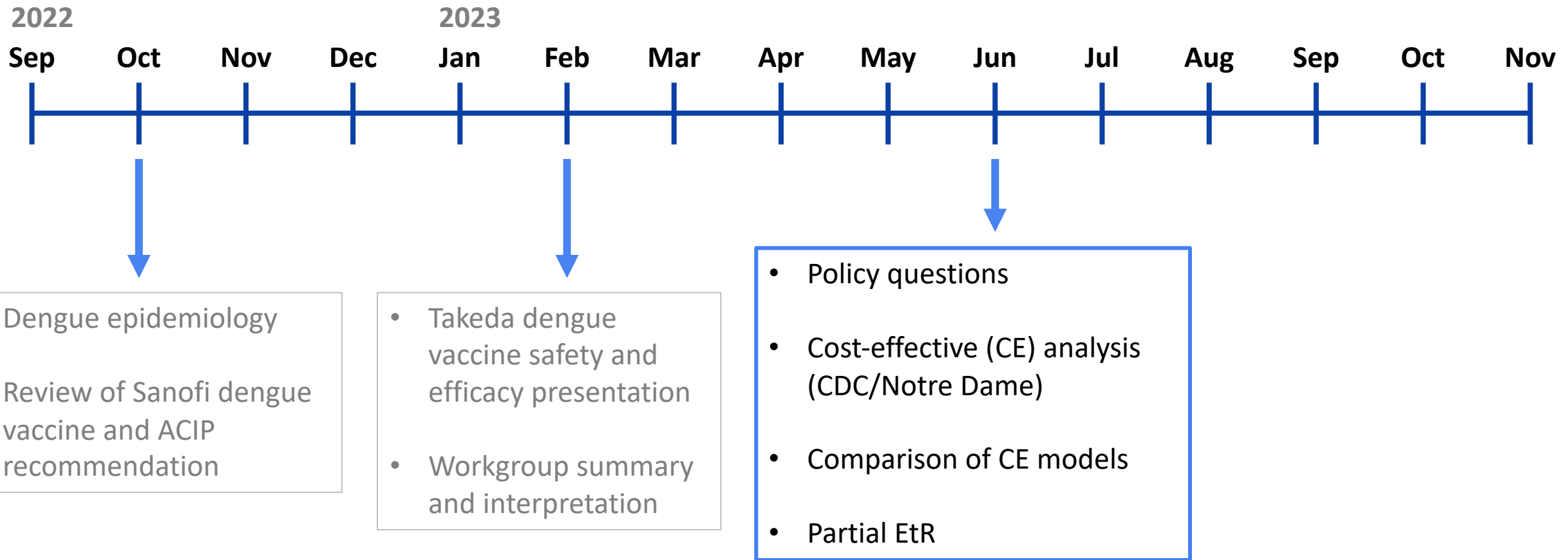
Three doses of Dengvaxia are indicated for the prevention of dengue disease caused by dengue virus serotypes 1, 2, 3, and 4 in people 9–16 years old with:

- laboratory confirmation of previous dengue virus infection

AND

- living in endemic areas.

Presentations to ACIP on TAK-003



Takeda Announces Voluntary Withdrawal of U.S. Biologics License Application (BLA) for Dengue Vaccine Candidate TAK-003



July 11, 2023



Share

OSAKA, Japan and CAMBRIDGE, Massachusetts, July 11, 2023 – Takeda ([TSE:4502/NYSE:TAK](#)) today announced that the Company has voluntarily withdrawn the U.S. Biologics License Application (BLA) for its dengue vaccine candidate, TAK-003, following discussions with the U.S. Food and Drug Administration (FDA) on aspects of data collection, which cannot be addressed within the current BLA review cycle. The future plan for TAK-003 in the U.S. will be further evaluated given the need for additional data to support the BLA. Takeda will continue to evaluate the future plan for TAK-003 in the U.S. and will provide updates as they become available.

[Takeda Announces Withdrawal of U.S. BLA for Dengue Vaccine Candidate](#)

Chikungunya Vaccine

Background

- In February 2023, FDA accepted Valneva's Biologics License Application (BLA) for their chikungunya vaccine and granted priority review, with licensure possible in August 2023
- No chikungunya vaccine ever licensed in United States or globally
- No existing ACIP chikungunya vaccine recommendations
- Chikungunya Vaccines Work Group is developing policy options for ACIP's consideration for use of chikungunya vaccine among U.S. persons at risk of chikungunya, including
 - Travelers
 - Laboratory workers
 - Residents of U.S. territories and states with, or at risk of, transmission

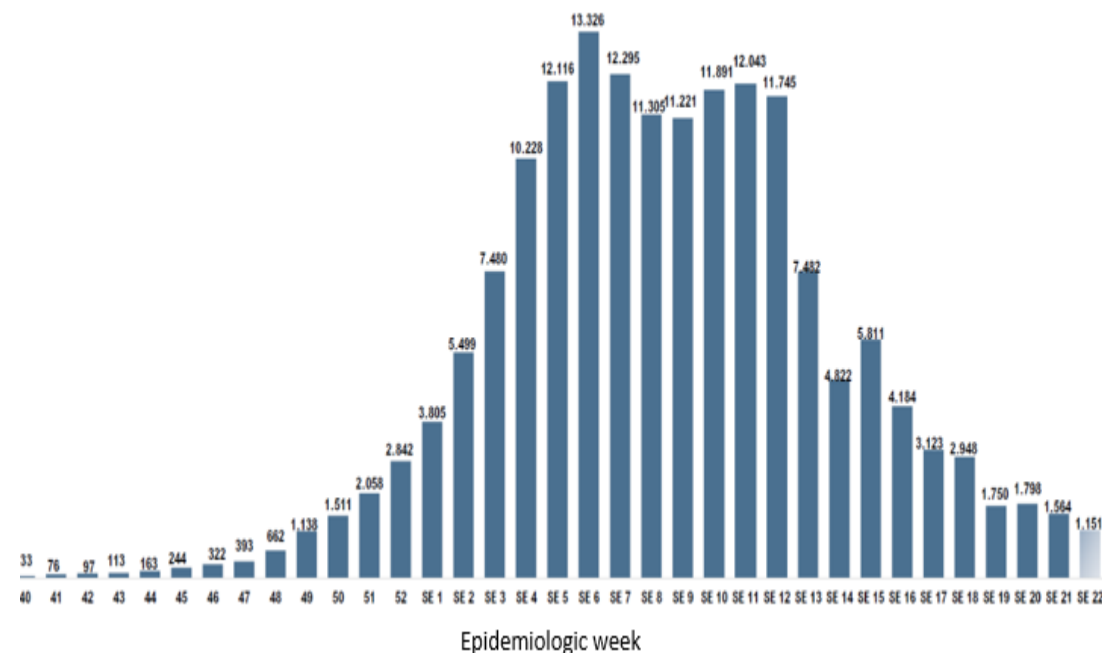
Chikungunya Infection in Laboratory Workers

- Laboratory workers at risk for chikungunya virus infection and disease
 - At least 44 reports, including 4 cases during the last 8 years
- Documented modes of transmission include aerosol and percutaneous routes
- Likelihood of disease vs. asymptomatic infection probably high



Chikungunya Outbreak in Paraguay, 2022-2023

- Since beginning in the last quarter of 2022, the outbreak has been explosive and extensive
- Groups at risk for severe disease include infants, older adults, and persons with comorbidities
- Case-fatality rate highest among neonates
- Impact on health services from patient load and sick staff



Source: Ministry of Public Health and Social Welfare, Paraguay

RSV Vaccines – Pediatric/Maternal

Evidence to Recommendations (EtR) Framework

Policy Question

- Should vaccination with Pfizer RSVPreF vaccine (120µg antigen, 1 dose IM given 24–36 weeks gestation) be recommended for pregnant people to prevent RSV disease in infants?

Summary of WG interpretations

- Efficacious vaccine that can prevent RSV lower respiratory tract infection in young infants
- WG expressed concern that the Pfizer trial was underpowered to detect a 20% difference in preterm births between vaccine and placebo recipients
- Interpretation of these overarching themes varied:
 - Some members of the WG expressed concern that the data were insufficient to determine the safety of this vaccine
 - Others stressed this vaccine can provide benefit by preventing RSV lower respiratory tract infection in infants and the difference in preterm births was not statistically significant

Summary of WG interpretations (cont.)

- Imbalance in preterm birth was most prominent in a single country, South Africa
- Imbalance in preterm births was not seen in high-income countries
- Imbalance was still present but less pronounced when comparing prevalence of low birth weight
- Most preterm births were >30 days after vaccination

Summary of WG interpretations (cont.)

- WG discussed considering a narrower recommended dosing window
 - Some expressed support for starting dosing at a later gestational age within 24–36-week window used in the trial as this could mitigate potential risk of early preterm birth until additional safety data are available
 - Others expressed concern that this could leave preterm infants who are at higher risk of severe RSV disease unprotected
- Aligning RSVpreF vaccine dosing during pregnancy with Tdap administration could improve feasibility
- All WG members endorsed the importance of post-introduction vaccine safety monitoring

Policy questions for ACIP vote

- Should vaccination with Pfizer RSVPreF vaccine (120µg antigen, 1 dose IM given 24-36 weeks gestation) be recommended for pregnant people to prevent RSV disease in infants?
- Should one dose of nirsevimab be recommended for infants born during or entering their first RSV season and <8 months of age at time of immunization?
- Should one dose of nirsevimab be recommended for children who are at increased risk of severe RSV disease entering their second RSV season and <20 months of age at time of immunization?

Draft clinical considerations if both RSVpreF and nirsevimab are licensed and recommended

- Either maternal vaccination with RSVpreF or nirsevimab is recommended to prevent RSV disease, but both products are not needed for most infants
- Risks and benefits of both RSVpreF and nirsevimab should be considered when deciding on maternal vaccination
- If mother vaccinated, nirsevimab can be considered if infant considered to have insufficient protection from vaccine or is at high risk of severe disease

Mpox Vaccines

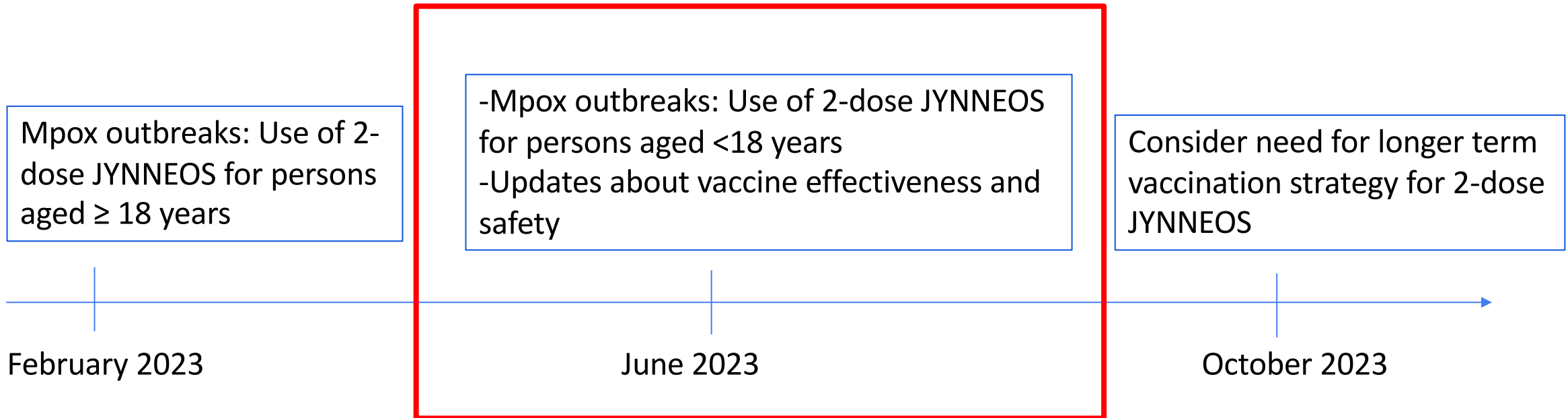
February 2023 ACIP meeting: Vote passed for use of JYNNEOS during outbreaks

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

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>

COVID-19 Vaccines

Work Group interpretation

COVID-19 in pregnant people and infants

- Pregnancy remains a risk factor for severe maternal disease and adverse pregnancy outcomes, even with new variants
- COVID-19 vaccination **improves outcomes** for pregnant people, their pregnancies and their infants
- Growing body of evidence that COVID-19 mRNA vaccines are **safe** during pregnancy¹
- Current uptake of updated COVID-19 vaccine is low among pregnant people
 - **23%** of pregnant people received an updated dose²
- Work group emphasized that pregnant people should receive recommended COVID-19 vaccine dose for protection of themselves and their infants
- Continue to review data and evaluate COVID-19 recommendations for pregnant people as needed

1. <https://www.cdc.gov/vaccinesafety/research/publications/index.html> . COVID-19 Vaccine Safety Articles and Studies by Topic. Pregnancy.

2. <https://covid.cdc.gov/covid-data-tracker/#vaccinations-pregnant-women>

Infection-induced and hybrid immunity

Summary

- Hybrid immunity likely provides better protection than either infection or vaccination alone
- Protection likely influenced by cumulative number of vaccine doses, number of times infected, timing of most recent vaccination or infection, and how closely the circulating variant matches the vaccine or prior infection
- Protection can wane over time after both infection and vaccination
- Receipt of updated vaccine dose can provide additional protection beyond that received by prior doses or infection and restore protection after waning

Steps toward recommendation of updated vaccine

- June 15, 2023 FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) met to discuss fall strain composition
- VRBPAC unanimously voted that the vaccine composition be updated to a monovalent COVID-19 vaccine with an XBB-lineage of the Omicron variant
- FDA advised manufacturers to develop vaccines with a monovalent XBB.1.5 composition
- Anticipate updated vaccine doses will be broadly available in the fall
- Following updated vaccine authorizations, ACIP will review evidence to inform updated recommendations

Planning for Fall 2023

- COVID-19 vaccines and treatments will likely transition to the commercial marketplace in fall 2023
 - CDC continues to partner closely with state, local, and interagency partners toward continued successful distribution of COVID-19 vaccines and treatments during this time, including clarification of processes for ordering, shipping and distribution
 - Guidance for partners will be published in summer 2023, prior to the transition to the commercial marketplace
- Most Americans will continue to pay nothing out-of-pocket for the COVID-19 vaccine due to their insurance coverage
- However, approximately 25 million uninsured adults will lose access to affordable COVID-19 vaccines and treatments if no action were taken
- The ***Bridge Access Program for COVID-19 Vaccines and Treatment*** is a public-private partnership which serves as a temporary measure to prevent the loss of under- and uninsured adults' access to COVID-19 vaccines and treatments at no-cost after commercialization

Summary

- COVID-19 continues to cause substantial morbidity and mortality across the population, particularly in groups like **older adults** and **persons with immunocompromising conditions**
- COVID-19 vaccines continue to be the **most effective tool** we have to prevent serious illness, hospitalization and death from COVID-19
- COVID-19 vaccination is important for **pregnant people** for the protection of themselves and their **infants**
- Most of the population hasn't received a bivalent vaccine dose
- Ongoing review of data to continue efforts toward simplification
 - Work Group would be supportive of additional simplification for children ages 2 – 4 years in the future
- FDA advised manufacturers to develop vaccines with a monovalent XBB.1.5 composition
- Anticipate benefits from updated vaccine prior to possible increases in cases over the winter; ACIP can discuss future vaccine recommendations at upcoming meetings following updated vaccine authorizations

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

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