Highlights from the October 2023 ACIP Meeting

Melinda Wharton, MD, MPH
Executive Secretary, Advisory Committee on Immunization Practices

National Network of Immunization Coalitions
November 15, 2023
Meningococcal Vaccines
ACIP is discussing two MenABCWY vaccines

<table>
<thead>
<tr>
<th>MenACWY component</th>
<th>MenB component</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer</td>
<td>Nimenrix™*</td>
<td>Trumemba®$</td>
</tr>
<tr>
<td>GSK</td>
<td>Menveo$</td>
<td>Bexero$</td>
</tr>
</tbody>
</table>

*not licensed in the United States

$ licensed in the United States
Policy Questions for Each Pentavalent Vaccine

- Should the pentavalent vaccine be included as an option for MenACWY/MenB vaccination in people currently recommended to receive both vaccines?
  — For example, 16 year olds

- Should the pentavalent vaccine be included as an option for people currently recommended to receive MenACWY only?
  — For example, 11–12 year olds

- Should the pentavalent vaccine be included as an option for people currently recommended to receive MenB only?
  — For example, the second dose of the MenB series

¹ 16 year olds who decide to receive the MenB vaccine based on shared clinical decision-making
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  - For example, the second dose of the MenB series

---

1 16 year olds who decide to receive the MenB vaccine based on shared clinical decision-making
ACIP Recommendation

Pfizer’s MenABCWY vaccine may be used when both MenACWY and MenB are indicated at the same visit.*

*1) Healthy individuals aged 16–23 years (routine schedule) when shared clinical decision-making favors administration of MenB vaccination, 2) individuals aged 10 years and older at increased risk of meningococcal disease (e.g., due to persistent complement deficiencies, complement inhibitor use, or functional or anatomic asplenia) due for both vaccines.
The Meningococcal Vaccines WG plans to revisit the schedule over the next year to ensure

- Adequate time to perform GRADE and EtR assessments
- Assessment of extended interval data for pentavalent vaccines
- Integration of any changes into the overall child and adolescent immunization schedule
- Assessment of post-COVID epidemiology
Proposed key questions

- Should the MenACWY series recommendations be changed to
  - Begin at an older age than currently recommended (11–12 years)
  - Eliminate the 11–12 year-old dose or change this recommendation to SCDM?

- Should the MenB series recommendations be changed to
  - Alter the recommended ages or dosing interval to provide better protection for individuals aged 18–19 years?
  - Revisit the SCDM recommendation for some or all adolescents (e.g., those planning to attend college)?

- Are there ways we can better integrate MenACWY and MenB vaccine schedules to streamline administration/increase feasibility?
Mpox Vaccine
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
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 ≥ 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
United States Mpox Case Counts Jan 1–Sept 28, 2023

7-day average of daily cases reported

N = 785

Subject to reporting irregularities

https://www.cdc.gov/poxvirus/mpox/response/2022/mpx-trends.html
ACIP recommends vaccination* with the 2-dose† JYNNEOS vaccine series for persons aged 18 years and older at risk for mpox§?

*Interim recommendation that ACIP will revisit in 2-3 years
† Dose 2 administered 28 days after dose 1
§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 ≥ 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
Tentative timeline for ACIP discussions and votes*

Interim routine recommendation and clinical guidance

October 2023

Publication of 2 MMWRs:
1) Use of JYNNEOS during mpox outbreaks
2) Use of JYNNEOS among persons at risk during the ongoing mpox outbreak

Early 2024

Consider results from NIH trial about use of JYNNEOS in persons aged 12-17 years

Possibly 2024

Review epidemiology, cost-effectiveness analysis, and other data to determine if routine recommendation should be continued

~2025/2026

*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
Respiratory Syncytial Virus Vaccines
In June 2023, CDC’s Advisory Committee on Immunization Practices (ACIP) voted to recommend that adults ages 60 years and older may receive a single dose of RSV vaccine using shared clinical decision making.

- **RSVPreF3** (Arexvy, GSK) is a 1-dose adjuvanted (AS01$_E$) recombinant prefusion F protein (prefF) vaccine.

- **RSVpreF** (Abrysvo, Pfizer) is a 1-dose recombinant prefF vaccine.

[https://www.cdc.gov/mmwr/volumes/72/wr/mm7229a4.htm](https://www.cdc.gov/mmwr/volumes/72/wr/mm7229a4.htm)
GSK: the humoral immune response to a single dose of RSVPreF3 in adults 50–59 years is non-inferior to that in adults 60 and older

- Humoral immune response* at day 31 after a single dose of RSVPreF3 in adults 60 and older compared to:
  - Adults 50–59, healthy (without prespecified conditions associated with increased risk of severe RSV disease)
    OR
  - Adults 50–59, at-increased-risk (AIR, with conditions associated with increased risk of severe RSV disease)
    • AIR conditions included: COPD resulting in activity restricting symptoms or use of long-term medication, chronic cardiovascular disease, diabetes mellitus type 1 or 2, chronic kidney disease, and chronic liver disease

- Cellular immune response appeared similar across groups, but was not statistically evaluated

- Safety profile of RSVPreF3 in adults 50–59 years similar to profile in 60 years and older

*The primary immunogenicity analysis of non-inferiority of the healthy and at-increased risk (AIR) 50–59 year-old group versus the established vaccine age group of 60 and older was based on geometric mean titer ratios and seroresponse rates. Data provided by GSK.
Adjusted RSV-associated hospitalization rates* per 100,000 adults ≥18 years by 5-year age group and year, RSV-NET, 2015–2016 to 2019–2020

*Unpublished data. Rates are adjusted for the frequency of RSV testing during each season and the sensitivity of RSV diagnostic tests.

*Clinical data were collected for all patients with laboratory-confirmed RSV hospitalizations during the 2014–2015 to 2017–2018 seasons, and for an age- and site-stratified random sample of patients with laboratory-confirmed RSV hospitalizations during the 2022–2023 season. Displayed percentages were weighted for the probability of selection.
Example *potential* policy options

<table>
<thead>
<tr>
<th>Current recommendation</th>
<th>Shared clinical decision-making</th>
</tr>
</thead>
<tbody>
<tr>
<td>Example 1</td>
<td>Shared clinical decision-making</td>
</tr>
<tr>
<td>Example 2</td>
<td>Risk-based</td>
</tr>
<tr>
<td>Example 3</td>
<td>Risk-based</td>
</tr>
<tr>
<td>Example 4</td>
<td>Risk-based</td>
</tr>
<tr>
<td>Example 5</td>
<td>Risk-based</td>
</tr>
</tbody>
</table>

Age (years)
Seasonal Influenza Vaccines
Vaccine Safety

- Safety of the quadrivalent recombinant influenza vaccine in pregnant women and their infants
- Pregnancy outcomes with cell culture-based quadrivalent inactivated influenza vaccine
- Safety of simultaneous versus sequential administration of mRNA COVID-19 vaccines and quadrivalent inactivated influenza vaccines
- Safety of simultaneous vaccination with zoster vaccine and quadrivalent adjuvanted influenza inactivated influenza vaccine
- Overview of recent studies on the safety of COVID-19 vaccine and influenza vaccine
WHO GISRS Influenza Surveillance
September 2017- August 2020

- Influenza B/Yamagata lineage viruses were the predominant B lineage circulating during the 2017-18 Northern Hemisphere and 2018 Southern Hemisphere seasons.
- 2018-2019 Northern Hemisphere had much less B activity overall and B/Victoria lineage viruses predominated.
- 2019 Southern Hemisphere showed regional differences in B lineage circulation with B/Yamagata mainly circulating in South America.
- 2019-20 Northern Hemisphere season began with an early B/Victoria lineage peak, followed by A(H1N1)pdm09.
- COVID-19 Pandemic and its mitigation saw a drop in influenza virus detection and circulation.
WHO GISRS Influenza Surveillance
September 2020- August 2023

Northern Hemisphere

- GISRS NICs continued influenza surveillance during the COVID-19 Pandemic
- Influenza continued to be detected but without seasonal peaks in epidemics until late 2021
- All influenza B activity due to B/Victoria lineage

Southern Hemisphere

- February 1 – August 31, 2023
- 1/3 of all viruses detected by GISRS were influenza B
- Parts of Northern Hemisphere saw second peak of activity due to B/Victoria and A(H1N1)pdm09 viruses
- Southern Hemisphere 2023 season co-circulation of B/Victoria and A(H1N1)pdm09 viruses

WHO Collaborating Center for Surveillance, Epidemiology and Control of Influenza,
Influenza Division, National Center for Immunization and Respiratory Diseases
WHO Vaccine Recommendations Summary

• The absence of confirmed detection of naturally occurring B/Yamagata lineage viruses is indicative of very low risk of infection by B/Yamagata lineage viruses.

• While influenza vaccines are safe and effective, the manufacture and use of inactivated and live attenuated vaccines containing B/Yamagata lineage viruses pose a theoretical risk of re-introduction of B/Yamagata lineage virus into the population. This risk can be mitigated by the removal of B/Yamagata lineage viruses from the vaccines.

• It was the opinion of the WHO influenza vaccine composition advisory committee that the inclusion of a B/Yamagata antigen as a component of influenza vaccines is no longer warranted, and every effort should be made to exclude this component as soon as practically possible.

• The committee recognizes that national or regional authorities are responsible for approving the composition and formulation of vaccines used in each country and should consider the use & relative benefit(s) of trivalent or quadrivalent influenza vaccines.
Immunization Schedules
Combined Immunization Schedules Work Group

- The Combined Immunization Schedule WG updates the immunization schedules annually.
  - Child and adolescent schedule (age birth through 18 years)
  - Adult schedule (age 19 years or older)

- The schedules are primarily designed to be a tool for healthcare providers to ensure individuals get all the vaccines they need when they need them.

Immunization Schedules | CDC
www.cdc.gov/vaccines/schedules/index.html
Impacts of Timeliness of Schedule Publication

- Insurance reimbursement

- The ability of certain health care providers to administer immunizations
  - Some states link pharmacists’ immunization authority to the schedule

- Health care provider knowledge and practices related to vaccine recommendations
<table>
<thead>
<tr>
<th>Vaccines and Other Immunizing Agents</th>
<th>Recommendations</th>
<th>Effective Date of Recommendation*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meningococcal Vaccines</td>
<td>Pfizer’s MenABCWY vaccine may be used when both MenACWY and MenB are indicated at the same visit.*</td>
<td>October 26, 2023</td>
</tr>
<tr>
<td></td>
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</tr>
<tr>
<td>Mpox Vaccines</td>
<td>ACIP recommends vaccination* with the 2-dose JYNNEOS vaccine series for persons aged 18 years and older at risk for mpox.†</td>
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<tr>
<td></td>
<td>†This is an interim recommendation that ACIP will revisit in 2-3 years</td>
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<tr>
<td></td>
<td>‡Dose 2 administered 28 days after dose 1</td>
<td></td>
</tr>
</tbody>
</table>
2024 immunization schedules: Publication Timeline

- October: ACIP vote approves the immunization schedules
- November: Professional organizations approve schedules
- December: Publish Schedules (web, app, pdf)
- January: Publish MMWR Notice to Readers, & Annals of Internal Medicine report published
- February:
# Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger

**United States 2024**

## Vaccines and Other Immunizing Agents in the Child and Adolescent Immunization Schedule

<table>
<thead>
<tr>
<th>Monovalent antibody</th>
<th>Abbreviation(s)</th>
<th>Trade name(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory syncytial virus (RSV)</td>
<td>RSV-IDb</td>
<td>Synmune®</td>
</tr>
</tbody>
</table>

## Vaccines

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Abbreviation(s)</th>
<th>Trade name(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>COVID-19</td>
<td>1′,2′-COV-mRNA</td>
<td>Comirnat®/Pzifer-BioNTech COVID-19 Vaccine</td>
</tr>
<tr>
<td>SARS-CoV-2/Moderna</td>
<td>COVID-19 mRNA Vaccine</td>
<td>SpikeVax®/Moderna</td>
</tr>
<tr>
<td>Dengue vaccine</td>
<td>DENV4CD</td>
<td>Dengvaxia®</td>
</tr>
<tr>
<td>Diphtheria, tetanus, and acellular pertussis vaccine</td>
<td>DTap</td>
<td>Ddap®, Infanrix®</td>
</tr>
<tr>
<td>Haemophilus influenzae type b vaccine</td>
<td>Hib (PRP-T)</td>
<td>ActHib®, HibTec-P®</td>
</tr>
<tr>
<td></td>
<td>Hib (PRP-OMP)</td>
<td>Pedia Hib®</td>
</tr>
<tr>
<td>Hepatitis A vaccine</td>
<td>HAV-A</td>
<td>Havia®</td>
</tr>
<tr>
<td>Hepatitis B vaccine</td>
<td>HB</td>
<td>Engerix®B, Recombivax HB®</td>
</tr>
<tr>
<td>Human papillomavirus vaccine</td>
<td>HPV</td>
<td>Gardasil®</td>
</tr>
<tr>
<td>Influenza vaccine (live, attenuated)</td>
<td>FLV</td>
<td>Fluvirin®</td>
</tr>
<tr>
<td>Influenza vaccine (killed, inactivated)</td>
<td>LAIV</td>
<td>FLUMA®/Flumist Quadrivalent</td>
</tr>
<tr>
<td>Measles, mumps, and rubella vaccine</td>
<td>MMR</td>
<td>M-M-R® Primovax®</td>
</tr>
<tr>
<td>Measles, mumps, rubella, and varicella vaccine</td>
<td>MMR+V</td>
<td>M-M-R-V® Primovax®</td>
</tr>
<tr>
<td>Measles, mumps, rubella, and varicella vaccine</td>
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<td>M-M-R-V® Primovax®</td>
</tr>
<tr>
<td>Influenza vaccine (killed, inactivated)</td>
<td>FLV</td>
<td>Fluvirin®</td>
</tr>
<tr>
<td>Respiratory syncytial virus vaccine</td>
<td>RSV</td>
<td>Synmune®</td>
</tr>
<tr>
<td>Rotavirus vaccine</td>
<td>RV</td>
<td>Rotarix®/Rotateq®</td>
</tr>
<tr>
<td>Tetanus, diphtheria, and acellular pertussis vaccine</td>
<td>Tdap</td>
<td>Adacel®/Boostrix®</td>
</tr>
<tr>
<td>Tetanus and diphtheria vaccine</td>
<td>Td</td>
<td>Td</td>
</tr>
<tr>
<td>Varicella vaccine</td>
<td>VAR</td>
<td>Varivax®</td>
</tr>
</tbody>
</table>

## How to use the child and adolescent immunization schedule

1. Determine recommended vaccine by age (Table 1).
2. Determine recommended interval for catch-up vaccination (Table 2).
3. Assess need for additional vaccination for medical condition or other contraindication (Table 3).
4. Review vaccine, frequencies, and intervals for specific conditions (Table 4).
5. Review contraindications for vaccine types (Appendix).

**Report**

- Suspected cases of reportable vaccine-preventable diseases or outbreaks to your state or local health department.
- Contact your state or local health department for information on reporting.

**Questions or comments**

Contact [www.cdc.gov/vaccines](http://www.cdc.gov/vaccines) or [800-232-2522](tel:8002322522), in English or Spanish, 8 a.m. – 8 p.m. ET, Monday through Friday, excluding holidays.

**Helpful information**

- Complete Advisory Committee on Immunization Practices (ACIP) recommendations: [www.cdc.gov/vaccines/recs/index.html](http://www.cdc.gov/vaccines/recs/index.html)
- ACIP Shared Clinical Decision-Making (ACDM) tool: [www.cdc.gov/vaccines/advice-acdmpadviceacdm.html](http://www.cdc.gov/vaccines/advice-acdmpadviceacdm.html)
- General Best Practice Guidelines for Immunization (including contraindications and precautions): [www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html](http://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html)
- Vaccine information statements: [www.cdc.gov/vaccines/hcp/pubs/downloads.html](http://www.cdc.gov/vaccines/hcp/pubs/downloads.html)

**U.S. Department of Health and Human Services**

Centers for Disease Control and Prevention

[Scan QR code for access to online schedule](http://www.cdc.gov/vaccines/)
<table>
<thead>
<tr>
<th>Vaccine</th>
<th>19–26 years</th>
<th>27–49 years</th>
<th>50–64 years</th>
<th>≥65 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>COVID-19</td>
<td>1 or more doses of updated (2023-2024 Formula) vaccine (See Notes)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Influenza inactivated (IVI) or influenza recombinant (IVR)</td>
<td>1 dose annually</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Influenza live, attenuated (LAIV)</td>
<td>1 dose annually</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory Syncytial Virus (RSV)</td>
<td></td>
<td>Seasonal administration during pregnancy. See Notes.</td>
<td></td>
<td>≥60 years</td>
</tr>
<tr>
<td>Tetanus, diphtheria, pertussis (Tdap or Td)</td>
<td>1 dose Tdap each pregnancy; 1 dose Td/Tdap for wound management (see notes)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mumps, rubella, rubella (MMR)</td>
<td></td>
<td>1 dose Tdap, then Td or Tdap booster every 10 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Varicella (VAR)</td>
<td>2 doses</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zoster recombinant (R2V)</td>
<td></td>
<td>2 doses for immunocompromising conditions (see notes)</td>
<td></td>
<td>2 doses</td>
</tr>
<tr>
<td>Human papillomavirus (HPV)</td>
<td>2 or 3 doses depending on age at initial vaccination or condition</td>
<td>27 through 45 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pneumococcal (PCV15, PCV20, PPV23)</td>
<td></td>
<td></td>
<td></td>
<td>See Notes</td>
</tr>
<tr>
<td>Hepatitis A (HepA)</td>
<td></td>
<td>2, 3, or 4 doses depending on vaccine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatitis B (HepB)</td>
<td></td>
<td>2, 3, or 4 doses depending on vaccine or condition</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Meningococcal A, C, W, Y (MenACWY)</td>
<td>1 or 2 doses depending on indication, see notes for booster recommendations</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Meningococcal B (MenB)</td>
<td>2 or 3 doses depending on vaccine and indication, see notes for booster recommendations</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neosporus influenza type b (Hib)</td>
<td>19 through 23 years</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Haemophilus influenzae type b (Hib)</td>
<td>1 or 3 doses depending on indication</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Recommended vaccination for adults who meet age requirement, lack documentation of vaccination, or lack evidence of past infection. Recommended vaccination for adults with an additional risk factor or another indication. Recommended vaccination based on shared clinical decision-making. No recommendation/Not applicable.
Chikungunya Vaccine
Chikungunya vaccine

- Live attenuated vaccine manufactured by Valneva
  - Single dose primary schedule
  - Initial application for adults aged ≥18 years
- Expected licensure date for Valneva’s chikungunya vaccine revised from August 2023 to November 2023
- 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
Draft recommendations

- Chikungunya vaccine is recommended for persons aged ≥18 years traveling to a country or territory where there is a chikungunya outbreak.

- In addition, chikungunya vaccine may be considered for the following persons traveling to a country or territory without an outbreak but with evidence of chikungunya virus transmission among humans within the last 5 years:
  - Older persons (e.g., >65 years), particularly those with underlying medical conditions, who are likely to have at least moderate exposure to mosquitoes.
  - Persons staying for a cumulative period of 6 months or more during a 2-year period.
Draft recommendation

Chikungunya vaccination is recommended for laboratory workers with potential for exposure to chikungunya virus
FDA Approves First Vaccine to Prevent Disease Caused by Chikungunya Virus

For Immediate Release:  November 09, 2023

Today, the U.S. Food and Drug Administration approved Ixchiq, the first chikungunya vaccine. Ixchiq is approved for individuals 18 years of age and older who are at increased risk of exposure to chikungunya virus.

The chikungunya virus is primarily transmitted to people through the bite of an infected mosquito. Chikungunya is an emerging global health threat with at least 5 million cases of chikungunya virus infection reported during the past 15 years. The highest risk of infection is in tropical and subtropical regions of Africa, Southeast Asia, and parts of the Americas where chikungunya virus-carrying mosquitoes are endemic. However, chikungunya virus has spread to new geographical areas causing a rise in global prevalence of the disease.
Dengue Vaccines
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.
TAK-003 is based on a live, attenuated DENV-2 virus backbone expressing E and prM proteins of all four DENV serotypes

Genetic structure and design of TAK-003


C, capsid; DENV, dengue virus; E, envelope; NS, non-structural; prM, pre-membrane; TDV, tetravalent dengue vaccine.
Summary of Work Group Interpretation – TAK-003

- Protects **seropositive** recipients against VCD and hospitalization due to any serotype.
- Protects **seronegative** recipients against VCD and hospitalization for DENV-1 or DENV-2.
- Does **NOT** protect **seronegative** recipients against VCD for DENV-3 and DENV-4.
- Vaccine efficacy against hospitalization for DENV-4 among **seronegative** recipients is unknown.
  - Only 1 DENV-4 hospitalization, limiting efficacy assessment.
- No efficacy against hospitalization for DENV-3 among **seronegative** vaccine recipients compared to placebo (-87.9%; 95% CI: -573.4–47.6%)
  - Data insufficient to rule out an increased risk among vaccine recipients.

VCD: Virologically-confirmed dengue
On July 11, Takeda voluntarily withdrew TAK-003 from FDA review

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

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 travelers and those living in dengue-endemic areas of the U.S., such as Puerto Rico. The vaccine is approved in multiple endemic and non-endemic countries, with more approvals expected over the coming years.
COVID-19 Vaccines
COVID-19 vaccine updates

- **September 11, 2023**
  - FDA authorized the updated mRNA COVID-19 vaccines for use in persons ages 6 months–11 years under emergency use authorizations (EUAs)
  - FDA approved the updated mRNA COVID-19 vaccines in persons ages ≥ 12 years under supplemental biologics license applications (BLAs)

- **September 12, 2023**
  - ACIP voted to recommend vaccination with updated (2023–2024 Formula) COVID-19 vaccines as authorized under EUA or approved by BLA in persons aged ≥6 months

- **October 3, 2023**
  - FDA authorized the updated (2023–2024 Formula) Novavax COVID-19 vaccine for use in persons aged ≥12 years under EUA

Note: Updated (2023 – 2024 Formula) COVID-19 vaccines are monovalent vaccines containing an XBB.1.5 component
Updated COVID-19 vaccines are available to most people living in the U.S. at no cost through their private health insurance, Medicare, and Medicaid plans.

**Private health insurance**
Plans that are ACA-compliant cover COVID-19 vaccines from an in-network provider at no cost-sharing.

**Medicare and Medicaid**
Cover COVID-19 vaccines at no-cost sharing

**Government programs**
Provide vaccine at no cost for:
- VFC: Children through 18 years that are Medicaid eligible, uninsured, American Indian/Alaska Native, or underinsured
- Bridge Access Program: Adults ages 18 years and older who are underinsured* or uninsured

*Adults with health insurance that does not cover all COVID-19 vaccine costs, at any Bridge Access Program site which is in-network for their health insurance.
COVID-19 vaccine doses from the same manufacturer should be administered whenever recommended. In the following circumstances, an age-appropriate COVID-19 vaccine from a different manufacturer may be administered:
- Same vaccine not available at the vaccination site at the time of the clinic visit
- Previous dose unknown
- Person would otherwise not receive a recommended vaccine dose
- Person starts but unable to complete a vaccination series with the same COVID-19 vaccine due to a contraindication

A Vaccine Adverse Event Reporting System (VAERS) report is not indicated in these circumstances.
Upcoming COVID-19 policy discussions

- Consideration of additional COVID-19 vaccine doses in older adults
  - Anticipated for February 2024 ACIP meeting
  - Policy discussion will occur prior to individuals reaching 6 months since their last dose

- Preparations for future COVID-19 vaccine formula updates
  - Discussions will begin at June 2024 ACIP meeting

- Continue to monitor vaccine effectiveness, vaccine safety, and COVID-19 epidemiology
  - COVID-19 vaccine recommendations can be updated if needed
Pneumococcal Vaccines
Invasive pneumococcal disease incidence among adults aged ≥65 years reached a historically low level early in the COVID-19 pandemic.

IPD = invasive pneumococcal disease
CDC Active Bacterial Core surveillance

IPV13: children
PCV13: adults
PCV15 & PCV20: adults
COVID-19
Approximately 40% of IPD cases in adults aged ≥65 years were caused by serotypes not contained in currently recommended vaccines.
# New Adult Pneumococcal Vaccines in Advanced Stages of Development

| 1  | 3  | 4  | 5 | 6 | 6 | 7 | 7 | 9 | 1 | 1  | 1 | 1 | 1 | 1 | 2 | 2 | 5 | 2 | 9 | 1 | 0 | 1 | 2 | 2 | 1 | 1  | 2  | 3 | 3 | 3 | 3 | 3 | 3 A | 3 B | 3 5 A | 3 B |
| PCV15 |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| PCV20 |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| PPSV23 |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| Pn-MAPS24v |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| VAX-24 |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| V116 |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |

## 24-valent pneumococcal vaccines
- Completed phase 1/2 study for adults\(^1\)
- Completed phase 1/2 studies for adults, undergoing phase 2 studies in infants\(^2\)

## 21-valent pneumococcal conjugate vaccine
- Completed phase 1/2 study for adults\(^3\)
- Phase 3 studies in adults are currently ongoing

Next Steps for Pneumococcal Vaccines Work Group

- Review evidence on use of **21-valent pneumococcal conjugate vaccine (V116)** for adults
  - Submission of a Biologics License Application for V116 to the FDA is anticipated in Q4 of 2023, with possible FDA approval in the first half of 2024
Next ACIP meeting: February 28-29, 2024