Highlights from the October 2023 ACIP Meeting

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

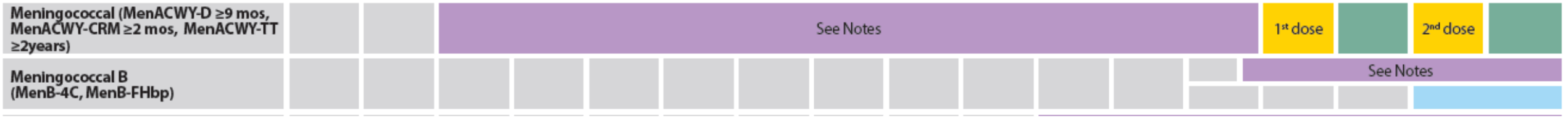
National Network of Immunization Coalitions
November 15, 2023

Meningococcal Vaccines

ACIP is discussing two MenABCWY vaccines

	MenACWY component	MenB component	Status
Pfizer	Nimenrix™*	Trumemba®§	Licensed October 20, 2023
GSK	Menveo§	Bexero§	Regulatory submission expected soon

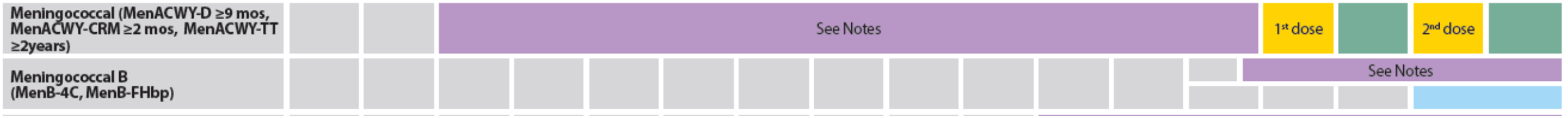
*not licensed in the United States
§ licensed in the United States



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[1]
- 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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- 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

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

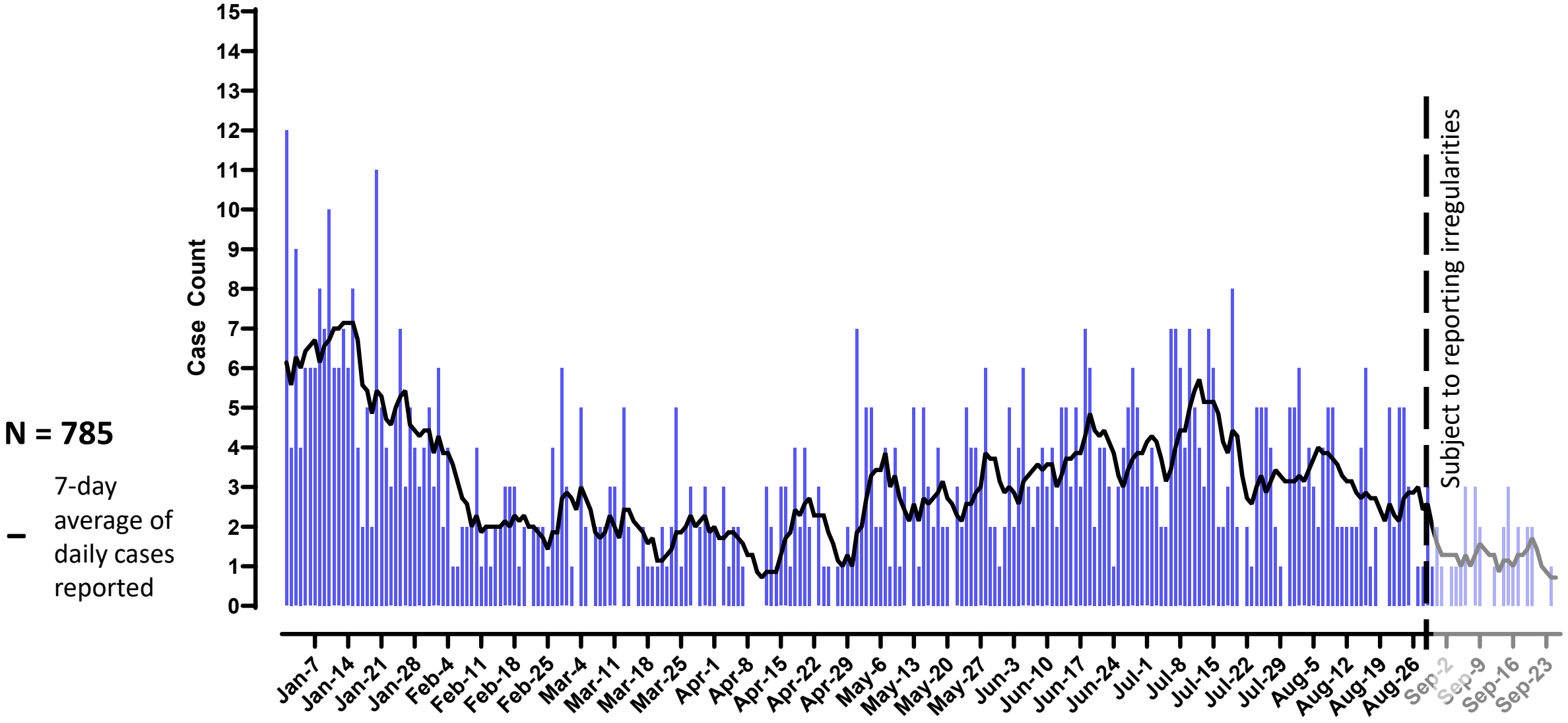
- Vote: ACIP recommends the 2-dose* JYNNEOS vaccine series for persons aged 18 years and older at risk of mpox during an mpox outbreak†

  *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



https://www.cdc.gov/poxvirus/mpox/response/2022/mpx-trends.html

ACIP recommendation

ACIP recommends vaccination* with the 2-dose† JYNNEOS vaccine series for persons aged 18 years and older at risk for mpox§?

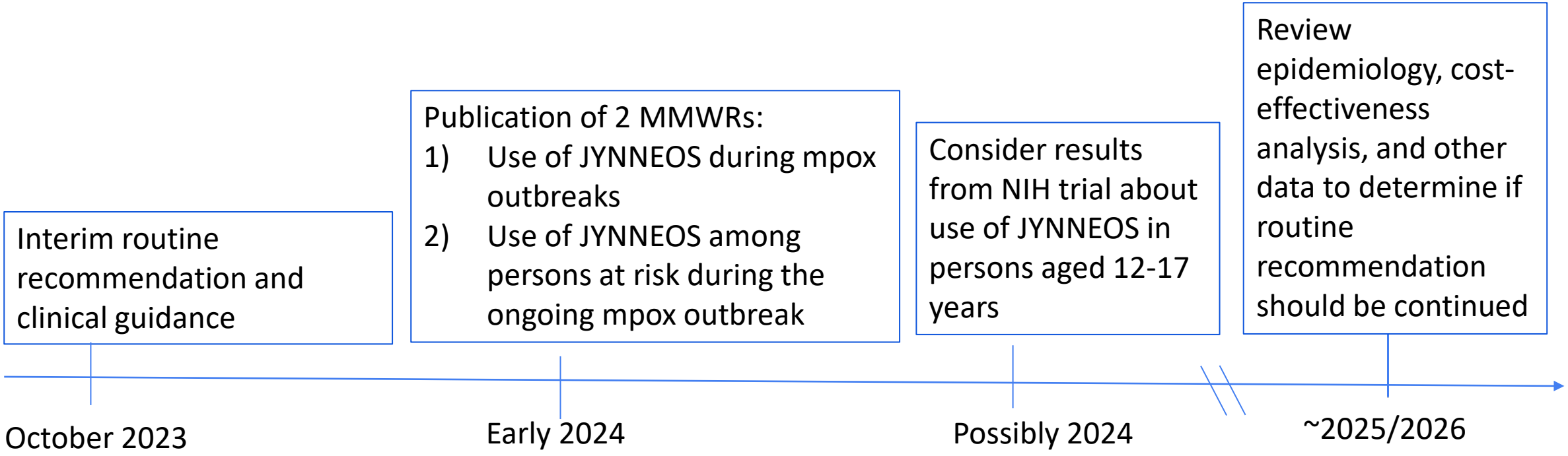
*Interim recommendation that ACIP will revisit in 2-3 years

† 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*



*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 (preF) vaccine.

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

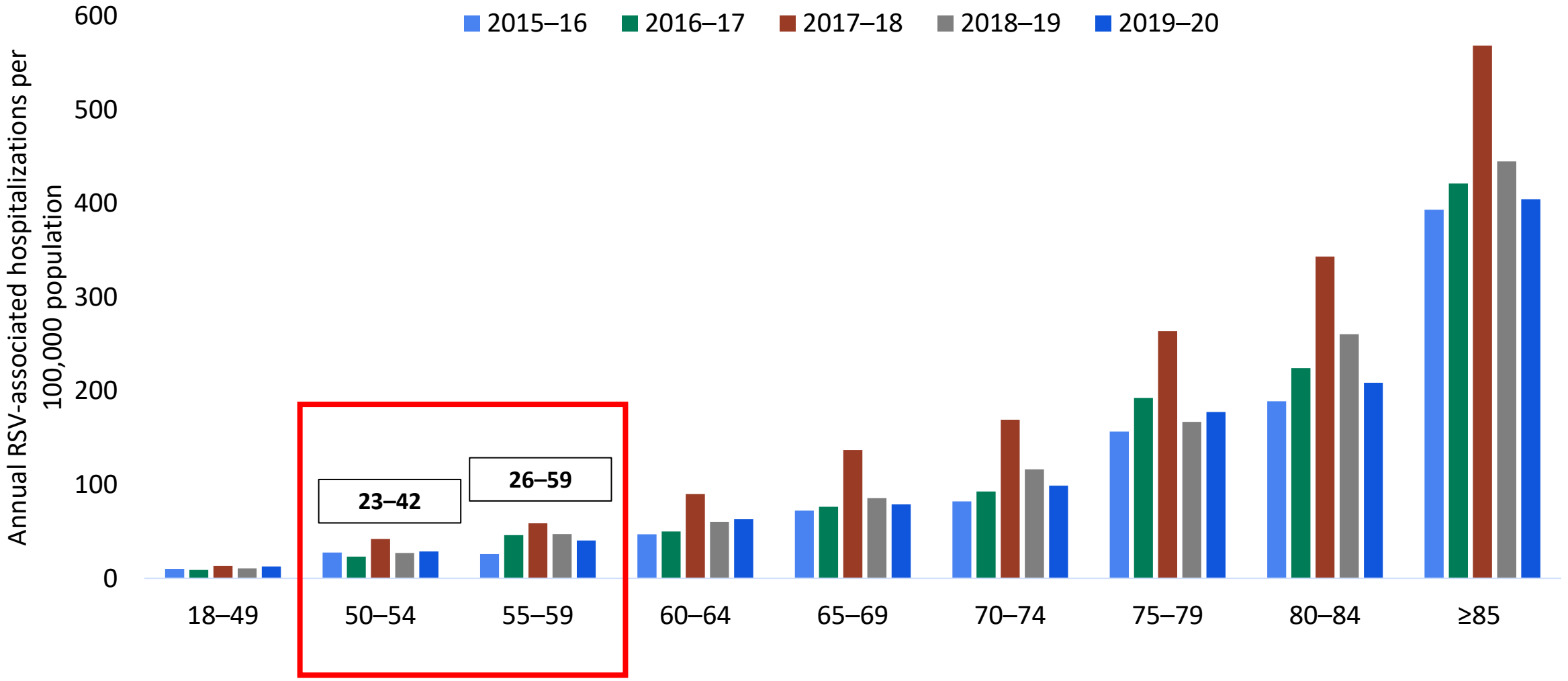
https://www.cdc.gov/mmwr/volumes/72/wr/mm7229a4.htm

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

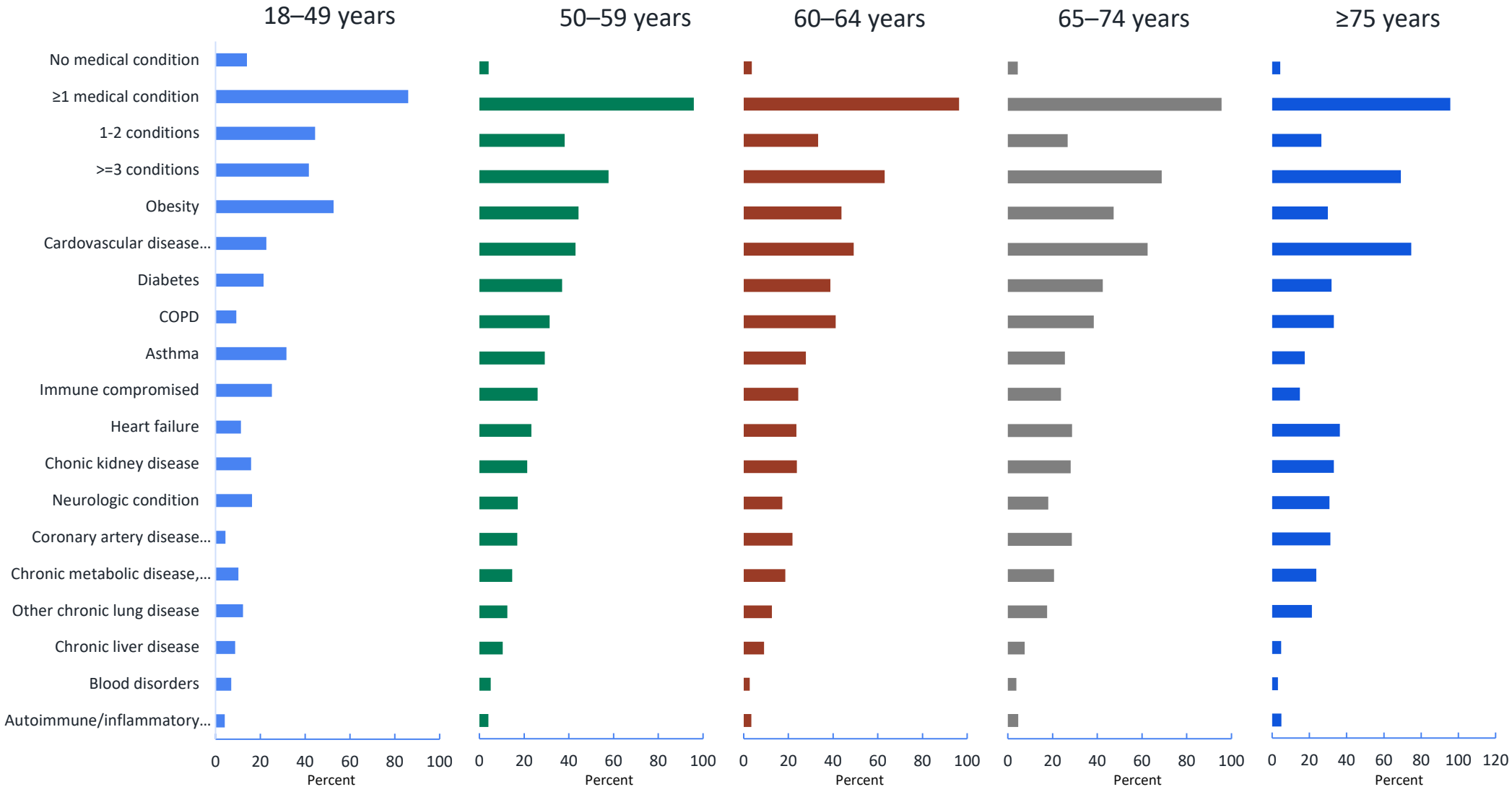
*The primary immunogenicity analysis of non-inferiority of the healthy and at-increased risk (AIR) 50–59 year-old group versus the established vaccine age group of 60 and older was based on geometric mean titer ratios and seroresponse rates. Data provided by GSK.

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



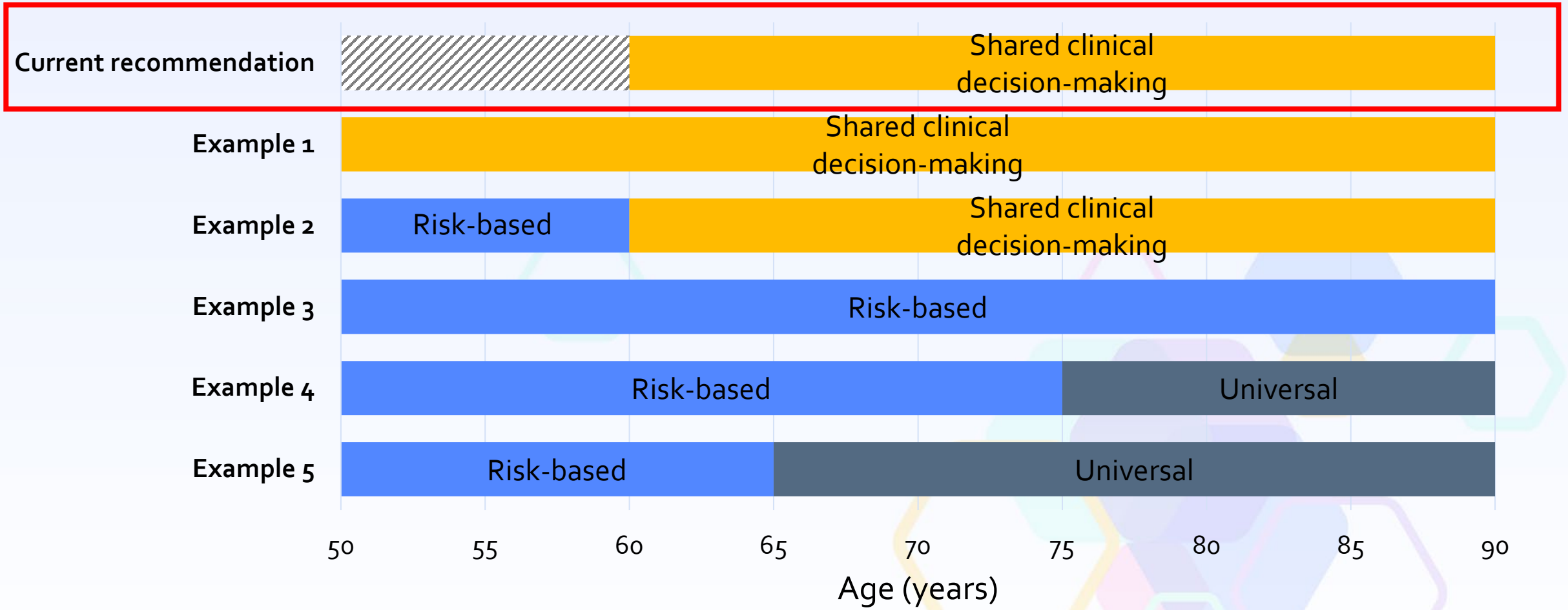
*Unpublished data. Rates are adjusted for the frequency of RSV testing during each season and the sensitivity of RSV diagnostic tests.

Frequency of underlying medical conditions among non-pregnant adults with RSV-associated hospitalizations by age group — RSV-NET, 2014–2015 to 2017–2018 and 2022–2023



*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



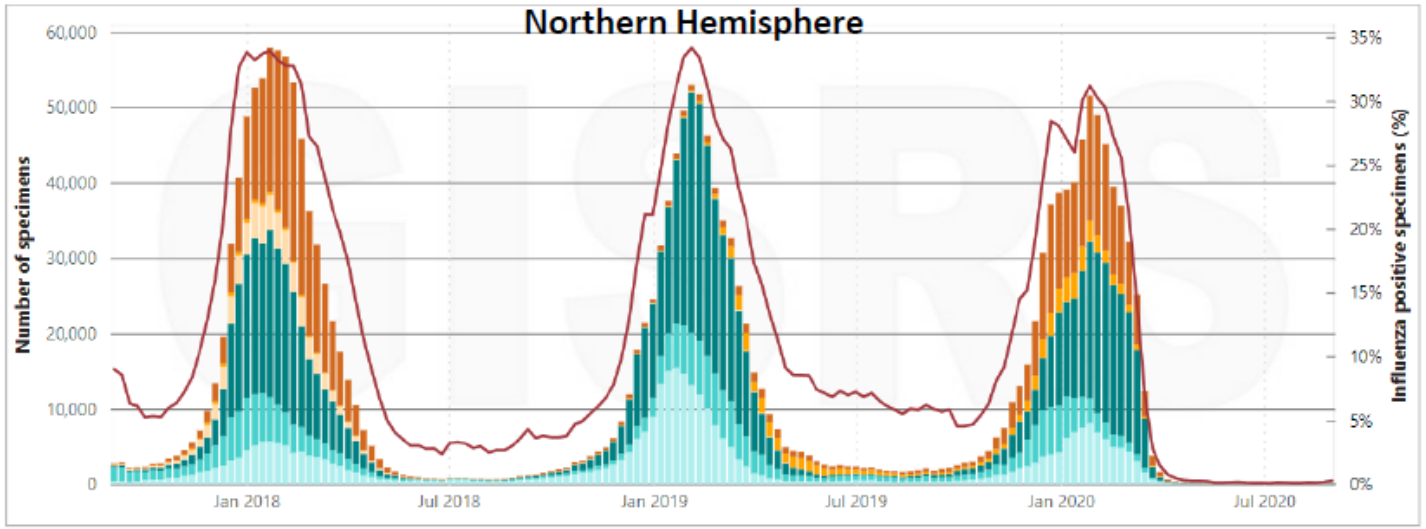
Seasonal Influenza Vaccines

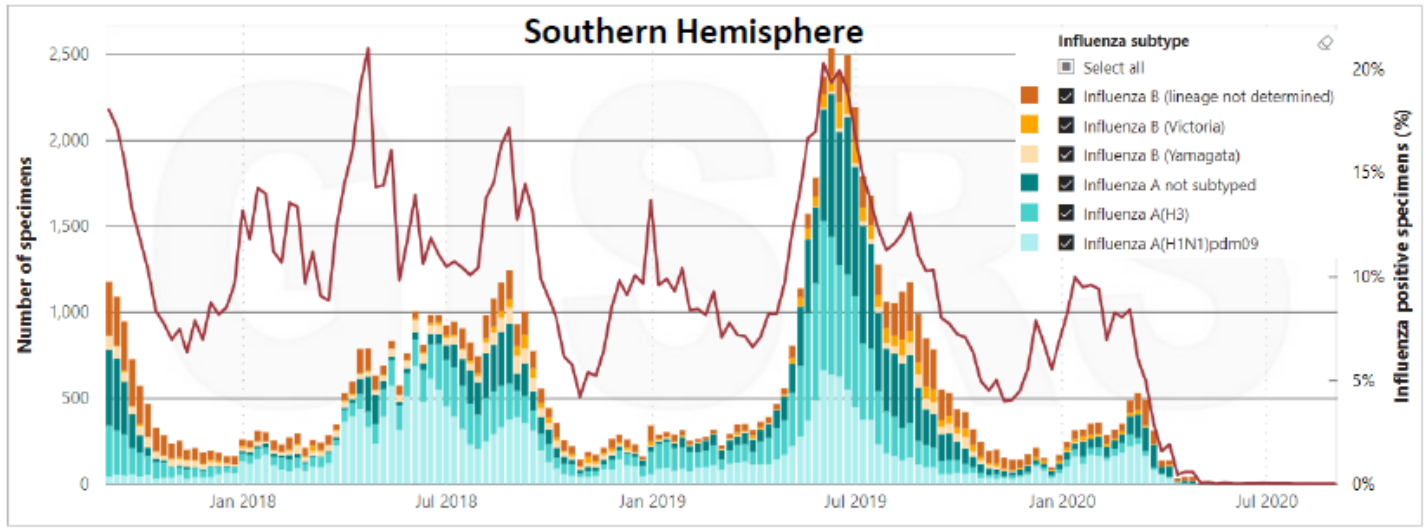
Vaccine Safety

- 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

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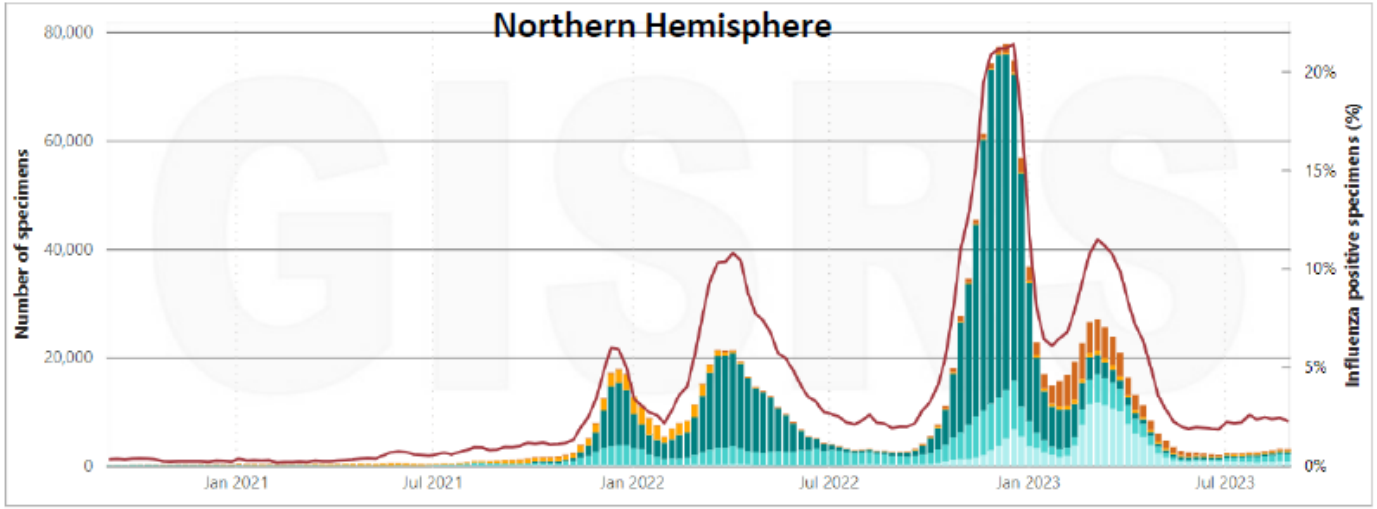
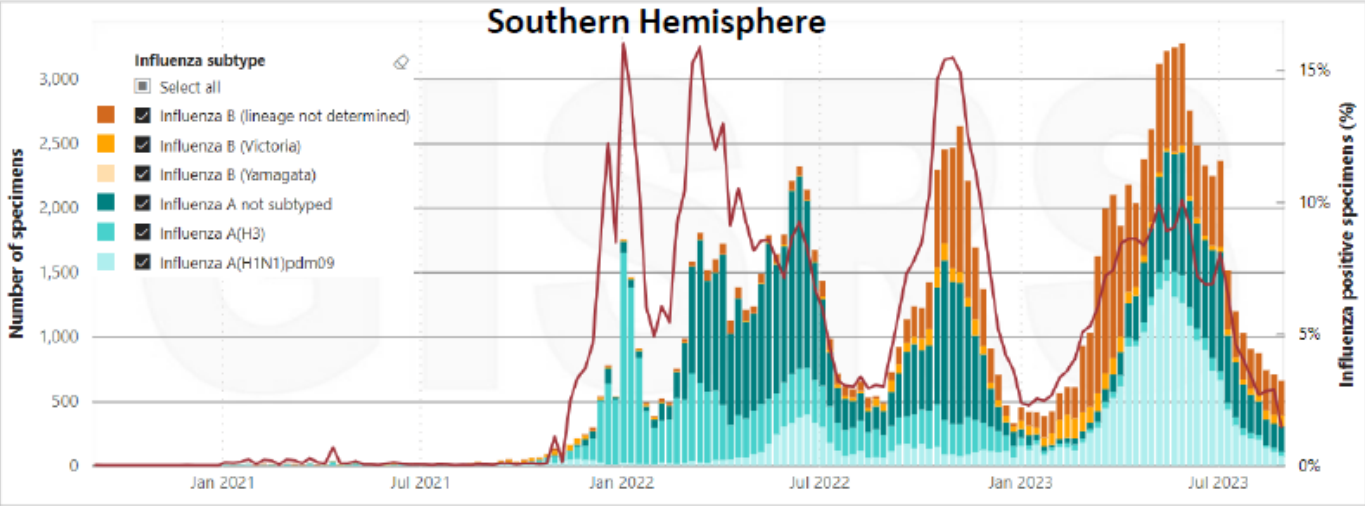
WHO GISRS Influenza Surveillance

September 2020- August 2023





- 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

- 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

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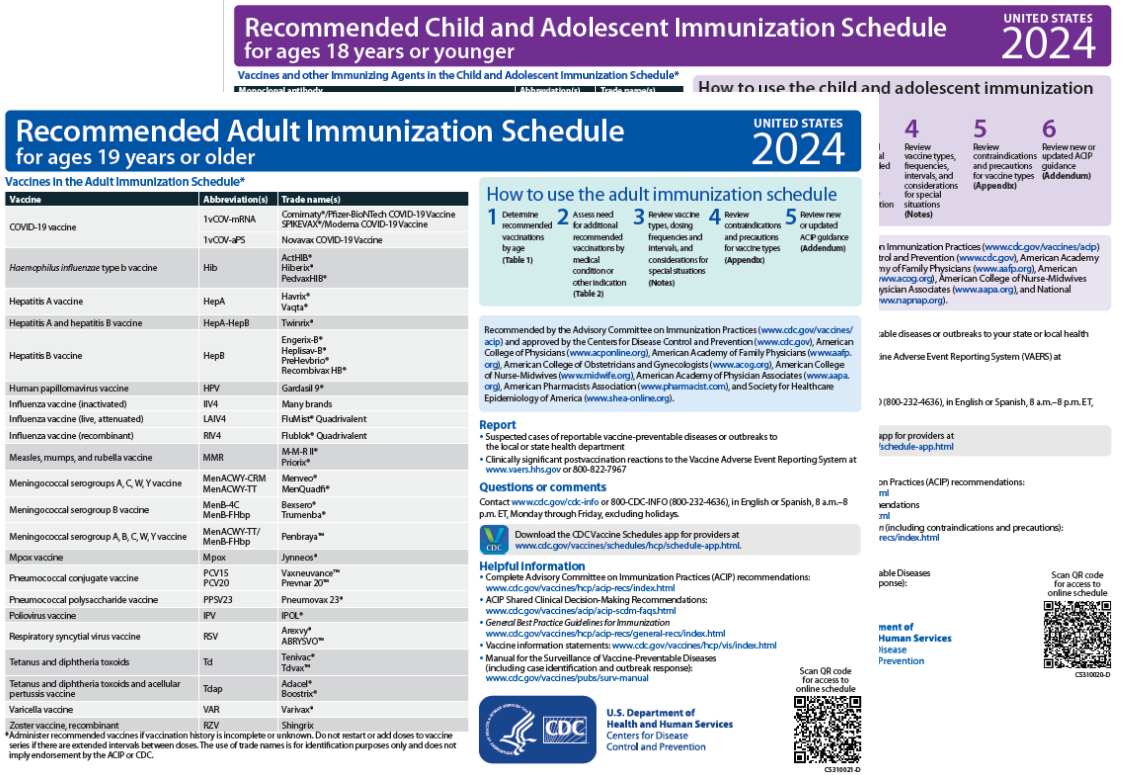
WHO Vaccine Recommendations Summary

- 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 reintroduction 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.



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*

How to use the child and adolescent immunization

Recommended Adult Immunization Schedule for ages 19 years or older — UNITED STATES 2024

Vaccines in the Adult Immunization Schedule*

Vaccine	Abbreviation(s)	Trade name(s)
COVID-19 vaccine	1vCOV-mRNA	Comirnaty®/Pfizer-BioNTech COVID-19 Vaccine SPIKEVAX®/Moderna COVID-19 Vaccine
	1vCOV-aPS	Novavax COVID-19 Vaccine
Haemophilus influenzae type b vaccine	Hib	ActHIB® Hiberix® PedvaxHIB®
Hepatitis A vaccine	HepA	Havrix® Vaqta®
Hepatitis A and hepatitis B vaccine	HepA-HepB	Twinrix®
Hepatitis B vaccine	HepB	Engerix-B® Heplisav-B® PreHevbrio® Recombivax HB®
Human papillomavirus vaccine	HPV	Gardasil 9®
Influenza vaccine (inactivated)	IIV4	Many brands
Influenza vaccine (live, attenuated)	LAIV4	FluMist® Quadrivalent
Influenza vaccine (recombinant)	RIV4	Flublok® Quadrivalent
Measles, mumps, and rubella vaccine	MMR	M-M-R II® Priorix®
Meningococcal serogroups A, C, W, Y vaccine	MenACWY-CRM MenACWY-TT	Menveo® MenQuadfi®
Meningococcal serogroup B vaccine	MenB-4C MenB-FHbp	Bexsero® Trumenba®
Meningococcal serogroup A, B, C, W, Y vaccine	MenACWY-TT/ MenB-FHbp	Penbraya™
Mpox vaccine	Mpox	Jynneos®
Pneumococcal conjugate vaccine	PCV15 PCV20	Vaxneuvance™ Prevnar 20™
Pneumococcal polysaccharide vaccine	PPSV23	Pneumovax 23®
Poliovirus vaccine	IPV	IPOL®
Respiratory syncytial virus vaccine	RSV	Arexvy® ABRYSVO™
Tetanus and diphtheria toxoids	Td	Tenivac® Tdvax™
Tetanus and diphtheria toxoids and acellular pertussis vaccine	Tdap	Adacel® Boostrix®
Varicella vaccine	VAR	Varivax®
Zoster vaccine, recombinant	RZV	Shingrix

* Administer recommended vaccines if vaccination history is incomplete or unknown. Do not restart or add doses to vaccine series if there are extended intervals between doses. The use of trade names is for identification purposes only and does not imply endorsement by the ACIP or CDC.

How to use the adult immunization schedule

1 Determine recommended vaccinations by age (Table 1)
2 Assess need for additional recommended vaccinations by medical condition or other indication (Table 2)
3 Review vaccine types, dosing frequencies and intervals, and considerations for special situations (Notes)
4 Review vaccine types, frequencies, intervals, and considerations for special situations (Notes)
5 Review contraindications and precautions for vaccine types (Appendix)
6 Review new or updated ACIP guidance (Addendum)

Recommended by the Advisory Committee on Immunization Practices (www.cdc.gov/vaccines/acip) and approved by the Centers for Disease Control and Prevention (www.cdc.gov), American College of Physicians (www.acponline.org), American Academy of Family Physicians (www.aafp.org), American College of Obstetricians and Gynecologists (www.acog.org), American College of Nurse-Midwives (www.midwife.org), American Academy of Physician Associates (www.aapa.org), American Pharmacists Association (www.pharmacist.com), and Society for Healthcare Epidemiology of America (www.shea-online.org).

Report
- Suspected cases of reportable vaccine-preventable diseases or outbreaks to the local or state health department
- Clinically significant postvaccination reactions to the Vaccine Adverse Event Reporting System at www.vaers.hhs.gov or 800-822-7967

Questions or comments
Contact www.cdc.gov/cdc-info or 800-CDC-INFO (800-232-4636), in English or Spanish, 8 a.m.–8 p.m. ET, Monday through Friday, excluding holidays.

Download the CDCVaccine Schedules app for providers at www.cdc.gov/vaccines/schedules/hcp/schedule-app.html.

Helpful information
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- *General Best Practice Guidelines for Immunization* www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html
- Vaccine information statements: www.cdc.gov/vaccines/hcp/vis/index.html
- Manual for the Surveillance of Vaccine-Preventable Diseases (including case identification and outbreak response): www.cdc.gov/vaccines/pubs/surv-manual

Scan QR code for access to online schedule

CS310020-D

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Immunization Schedules | CDC
www.cdc.gov/vaccines/schedules/index.html

Impacts of Timeliness of Schedule Publication

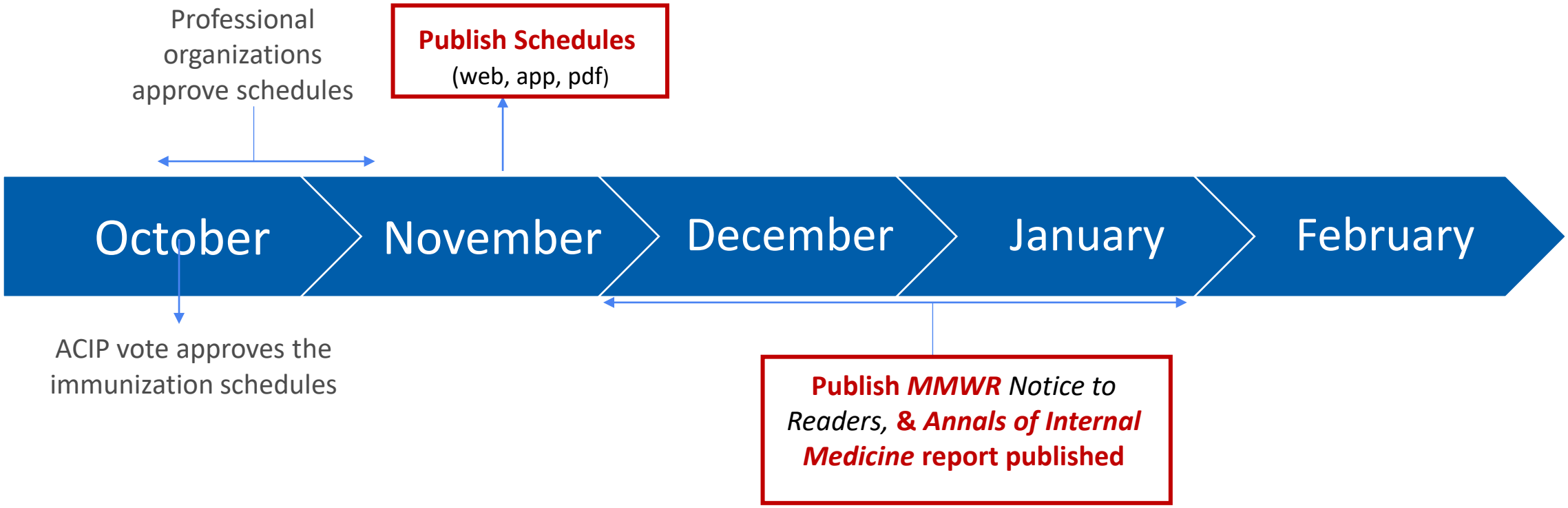
- **Insurance reimbursement**
- **The ability of certain health care providers to administer immunizations**
  - Some states link pharmacists' immunization authority to the schedule
- **Health care provider knowledge and practices related to vaccine recommendations**

Addendum – Child and Adolescent Recommended Immunization Schedule for ages 18 years or younger, United States, 2023

Vaccines and Other Immunizing Agents	Recommendations	Effective Date of Recommendation*
Meningococcal Vaccines	Pfizer's MenABCWY vaccine may be used when both MenACWY and MenB are indicated at the same visit.* *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.	October 26, 2023
Mpox Vaccines	ACIP recommends vaccination* with the 2-dose§ JYNNEOS vaccine series for persons aged 18 years and older at risk for mpox¶ *This is an interim recommendation that ACIP will revisit in 2-3 years §Dose 2 administered 28 days after dose 1	October 26, 2023

Birth-18 Years Immunization Schedule, By Medical Condition | CDC

2024 immunization schedules: Publication Timeline



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*

Monoclonal antibody	Abbreviation(s)	Trade name(s)
Respiratory syncytial virus monoclonal antibody (Nirsevimab)	RSV-mAb	Beyfortus™
Vaccine	**Abbreviation(s)**	**Trade name(s)**
COVID-19	1vCOV-mRNA	Comirnaty®/Pfizer-BioNTech COVID-19 Vaccine
		SPIKEVAX®/Moderna COVID-19 Vaccine
	1vCOV-aPS	Novavax COVID-19 Vaccine
Dengue vaccine	DEN4CYD	Dengvaxia®
Diphtheria, tetanus, and acellular pertussis vaccine	DTaP	Daptacel® Infanrix®
Haemophilus influenzae type b vaccine	Hib (PRP-T)	ActHIB® Hiberix®
	Hib (PRP-OMP)	PedvaxHIB®
Hepatitis A vaccine	HepA	Havrix® Vaqta®
Hepatitis B vaccine	HepB	Engerix-B® Recombivax HB®
Human papillomavirus vaccine	HPV	Gardasil 9®
Influenza vaccine (inactivated)	IIV4	Multiple
Influenza vaccine (live, attenuated)	LAIV4	FluMist® Quadrivalent
Measles, mumps, and rubella vaccine	MMR	M-M-R II® Priorix®
Meningococcal serogroups A, C, W, Y vaccine	MenACWY-CRM	Menveo®
	MenACWY-TT	MenQuadfi®
Meningococcal serogroup B vaccine	MenB-4C	Bexsero®
	MenB-FHbp	Trumenba®
Meningococcal serogroup A, B, C, W, Y vaccine	MenACWY-TT/ MenB-FHbp	Penbraya™
Mpox vaccine	Mpox	Jynneos®
Pneumococcal conjugate vaccine	PCV15	Vaxneuvance™
	PCV20	Prevnar 20®
Pneumococcal polysaccharide vaccine	PPSV23	Pneumovax 23®
Poliovirus vaccine (inactivated)	IPV	IPOL®
Respiratory syncytial virus vaccine	RSV	Abrysvo™
Rotavirus vaccine	RV1	Rotarix®
	RV5	RotaTeq®
Tetanus, diphtheria, and acellular pertussis vaccine	Tdap	Adacel® Boostrix®
Tetanus and diphtheria vaccine	Td	Tenivac® Tdvax™
Varicella vaccine	VAR	Varivax®
Combination vaccines *(use combination vaccines instead of separate injections when appropriate)*		
DTaP, hepatitis B, and inactivated poliovirus vaccine	DTaP-HepB-IPV	Pediarix®
DTaP, inactivated poliovirus, and *Haemophilus influenzae* type b vaccine	DTaP-IPV/Hib	Pentacel®
DTaP and inactivated poliovirus vaccine	DTaP-IPV	Kinrix® Quadracel®
DTaP, inactivated poliovirus, *Haemophilus influenzae* type b, and hepatitis B vaccine	DTaP-IPV-Hib-HepB	Vaxelis®
Measles, mumps, rubella, and varicella vaccine	MMRV	ProQuad®

*Administer recommended vaccines if immunization history is incomplete or unknown. Do not restart or add doses to vaccine series for extended intervals between doses. When a vaccine is not administered at the recommended age, administer at a subsequent visit.
The use of trade names is for identification purposes only and does not imply endorsement by the ACIP or CDC.

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 recommended vaccines by medical condition or other indication **(Table 3)**
4. Review vaccine types, frequencies, intervals, and considerations for special situations **(Notes)**
5. Review contraindications and precautions for vaccine types **(Appendix)**
6. Review new or updated ACIP guidance **(Addendum)**

Recommended by the Advisory Committee on Immunization Practices (www.cdc.gov/vaccines/acip) and approved by the Centers for Disease Control and Prevention (www.cdc.gov), American Academy of Pediatrics (www.aap.org), American Academy of Family Physicians (www.aafp.org), American College of Obstetricians and Gynecologists (www.acog.org), American College of Nurse-Midwives (www.midwife.org), American Academy of Physician Associates (www.aapa.org), and National Association of Pediatric Nurse Practitioners (www.napnap.org).

Report

- Suspected cases of reportable vaccine-preventable diseases or outbreaks to your state or local health department
- Clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or 800-822-7967

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- ACIP Shared Clinical Decision-Making Recommendations www.cdc.gov/vaccines/acip/acip-scdm-faqs.html
- *General Best Practice Guidelines for Immunization* (including contraindications and precautions): www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html
- Vaccine information statements: www.cdc.gov/vaccines/hcp/vis/index.html
- Manual for the Surveillance of Vaccine-Preventable Diseases (including case identification and outbreak response): www.cdc.gov/vaccines/pubs/surv-manual

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Table 1 Recommended Adult Immunization Schedule by Age Group, United States, 2024

Vaccine	19–26 years	27–49 years	50–64 years	≥65 years
COVID-19	1 or more doses of updated (2023-2024 Formula) vaccine (See Notes)			
Influenza inactivated (IIV4) or Influenza recombinant (RIV4)	1 dose annually			
or	or			
Influenza live, attenuated (LAIV4)	1 dose annually			
Respiratory Syncytial Virus (RSV)	Seasonal administration during pregnancy. See Notes.			≥60 years
Tetanus, diphtheria, pertussis (Tdap or Td)	1 dose Tdap each pregnancy; 1 dose Td/Tdap for wound management (see notes)			
	1 dose Tdap, then Td or Tdap booster every 10 years			
Measles, mumps, rubella (MMR)	1 or 2 doses depending on indication (if born in 1957 or later)			For healthcare personnel, see notes
Varicella (VAR)	2 doses (if born in 1980 or later)		2 doses	
Zoster recombinant (RZV)	2 doses for immunocompromising conditions (see notes)		2 doses	
Human papillomavirus (HPV)	2 or 3 doses depending on age at initial vaccination or condition	27 through 45 years		
Pneumococcal (PCV15, PCV20, PPSV23)				See Notes
				See Notes
Hepatitis A (HepA)	2, 3, or 4 doses depending on vaccine			
Hepatitis B (HepB)	2, 3, or 4 doses depending on vaccine or condition			
Meningococcal A, C, W, Y (MenACWY)	1 or 2 doses depending on indication, see notes for booster recommendations			
Meningococcal B (MenB)	19 through 23 years	2 or 3 doses depending on vaccine and indication, see notes for booster recommendations		
Haemophilus influenzae type b (Hib)	1 or 3 doses depending on indication			
Mpox				

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 NEWS RELEASE

FDA Approves First Vaccine to Prevent Disease Caused by Chikungunya Virus

For Immediate Release: November 09, 2023

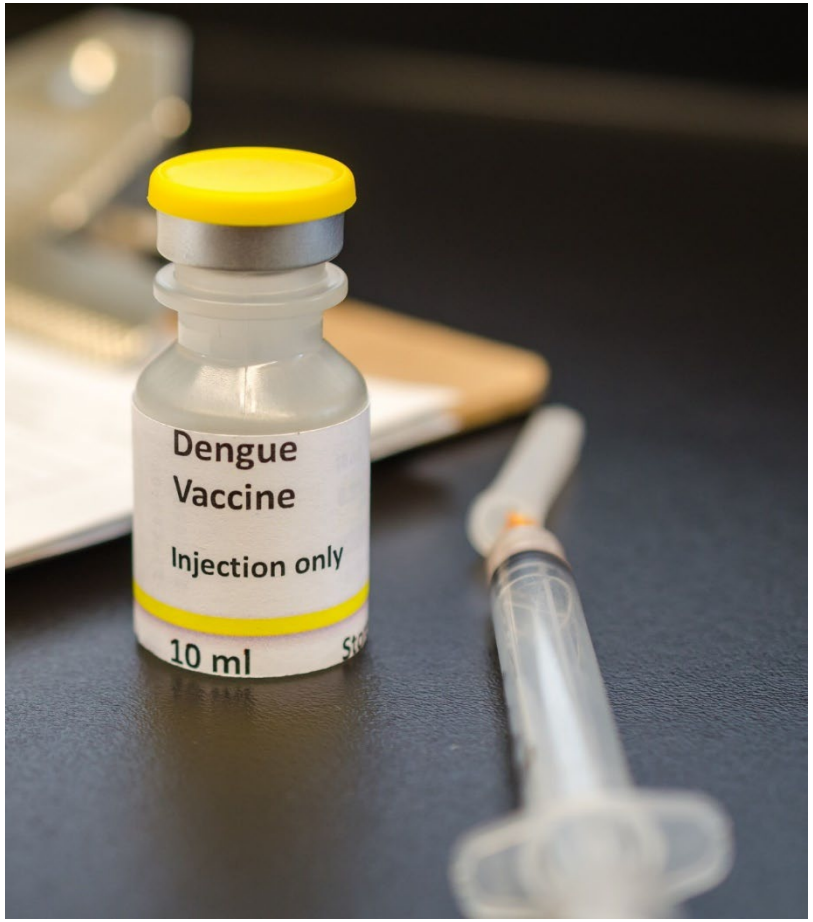
Español

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 mosquitos are endemic. However, chikungunya virus has spread to new geographical areas causing a rise in global prevalence of the disease.

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:

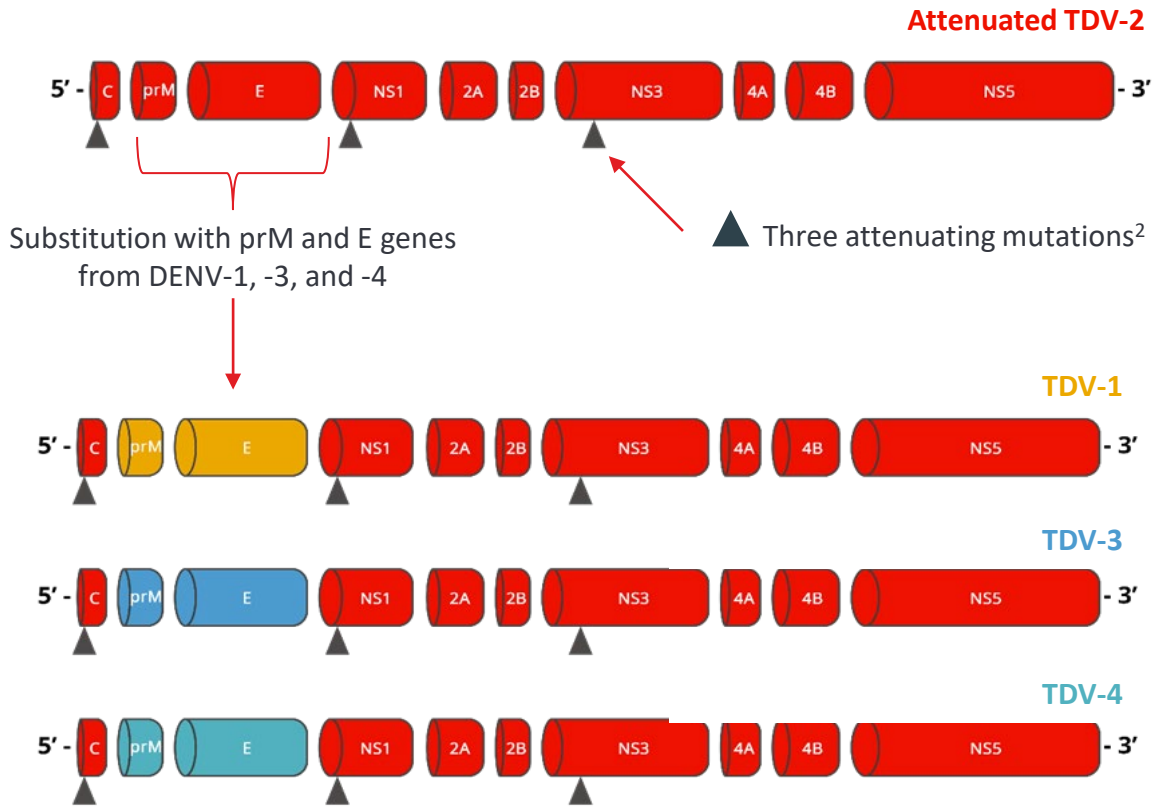
- laboratory confirmation of previous dengue virus infection

AND

- living in endemic areas.

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[1–3]



C, capsid; DENV, dengue virus; E, envelope; NS, non-structural; prM, pre-membrane; TDV, tetravalent dengue vaccine.

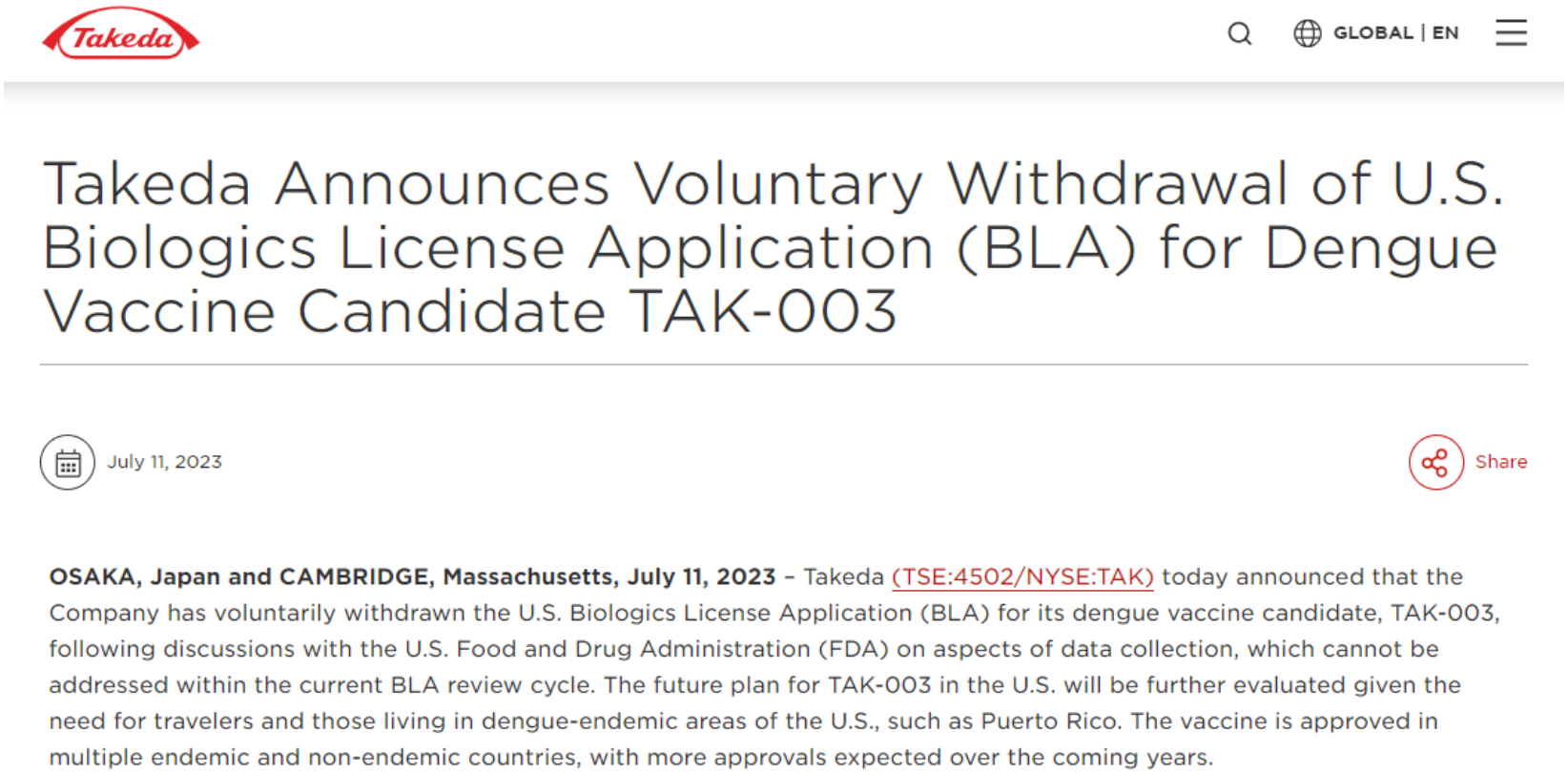
1. Osorio JE, et al. *Expert Rev Vaccines* 2016;15:497–508; 2. Osorio JE, et al. *Vaccine* 2015;33:7112–7120; 3. Patel SS, et al. *Clin Infect Dis* 2022. doi:10.1093/cid/ciac418 [Epub ahead of print].

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

GLOBAL | EN

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 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.

https://www.takeda.com/newsroom/statements/2023/takeda-announces-voluntary-withdrawal-of-US-biologics-license-application-for-dengue-vaccine-candidate-TAK-003/

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

Vaccine Cost/Insurance

- 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.

Updated Version of Interim Clinical Considerations on Interchangeability of COVID-19 vaccines

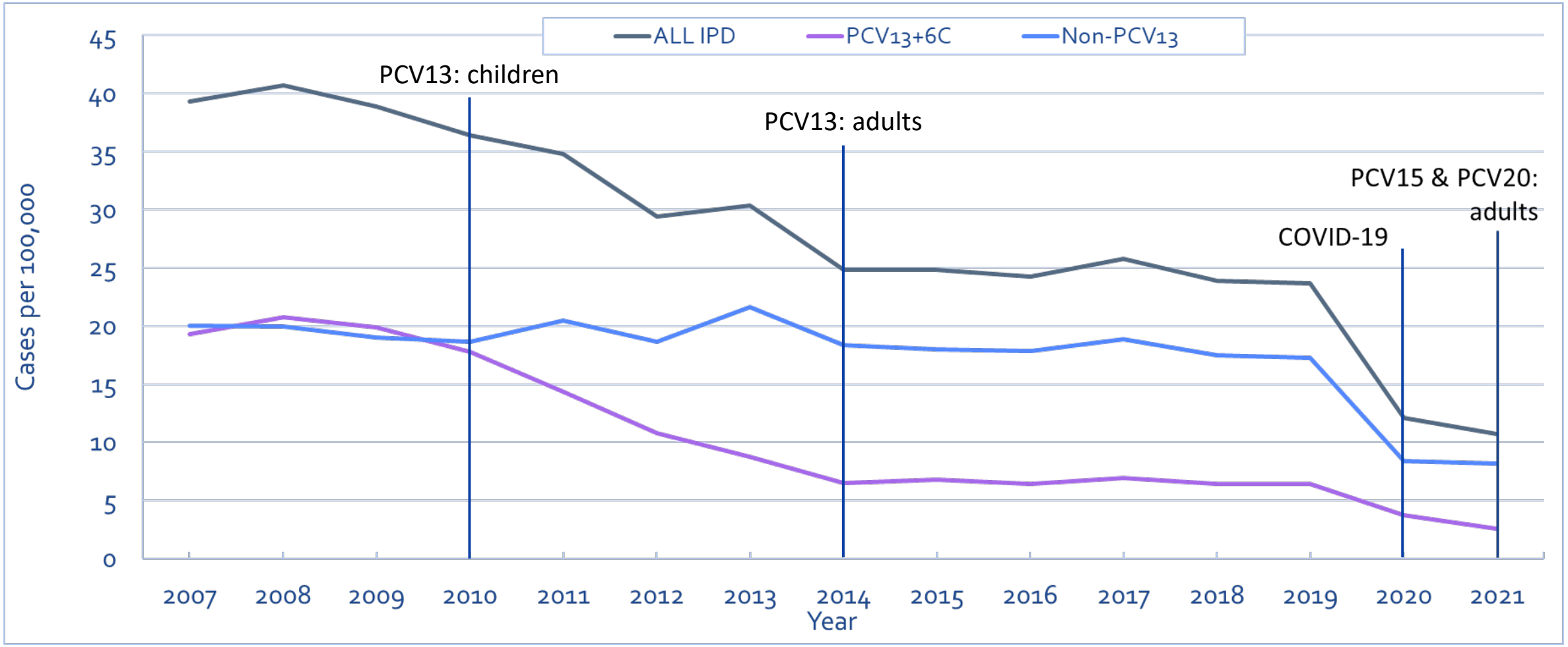
- COVID-19 vaccine doses from the same manufacturer should be administered whenever recommended. In the following **circumstances**, an age-appropriate COVID-19 vaccine from a different manufacturer may be administered:
  - Same vaccine not available **at the vaccination site at the time of the clinic 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

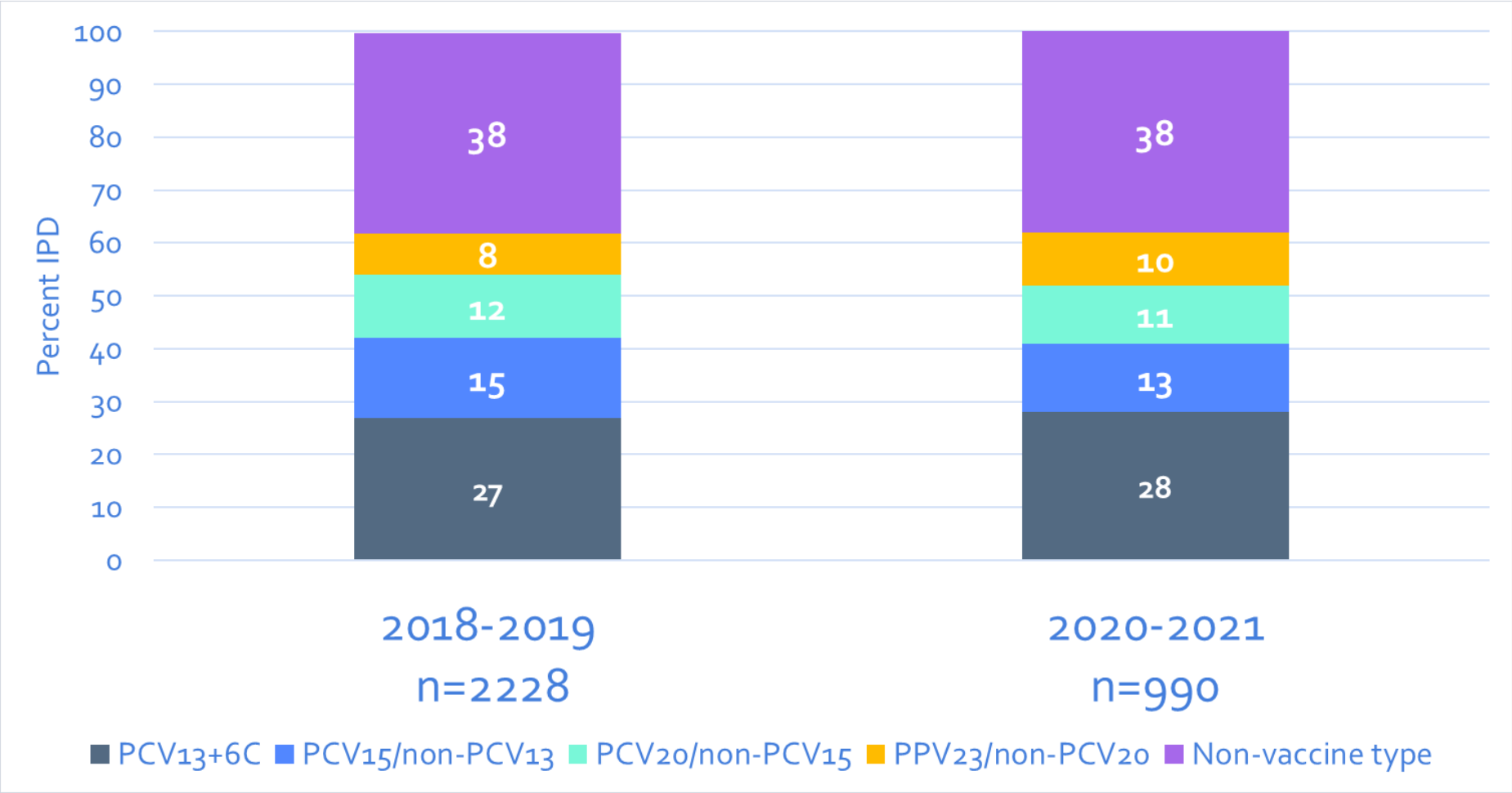
Invasive pneumococcal disease incidence among adults aged ≥65 years reached a historically low level early in the COVID-19 pandemic



IPD=invasive pneumococcal disease

CDC Active Bacterial Core surveillance

Approximately 40% of IPD cases in adults aged ≥65 years were caused by serotypes not contained in currently recommended vaccines



CDC Active Bacterial Core surveillance

New Adult Pneumococcal Vaccines in Advanced Stages of Development

	1	3	4	5	6A	6B	7F	9V	14	18C	19A	19F	23F	22F	33F	8	10A	11A	12F	15B	2	9N	17F	20	15A	15C	16F	23A	23B	24F	31	35B
PCV15																																
PCV20																																
PPSV23																																
Pn-MAPS24v																								20B								
VAX-24																								20B								
V116																								20A								

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]

Pn-MAPS24v, GSK

VAX-24, Vaxcyte

21-valent pneumococcal conjugate vaccine

- Completed phase 1/2 study for adults[3]
- Phase 3 studies in adults are currently ongoing

V116, Merck

1. Chichili et al. Vaccine 2022; 2.ClinicalTrials.gov ID: NCT05266456, NCT05297578, and NCT05844423; 3. Platt et al. Lancet ID 2022.

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

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