

Immunization Update

Olivia Kinney, PharmD, MS
National Pharmacy Practice Manager
Kroger Health



2024 Midyear Meeting & Trade Show
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Disclosure Statement

Olivia Kinney has consulted for Pfizer, Moderna, and Janssen. All relevant financial relationships listed have been mitigated.

None of the planners for this activity have relevant financial relationships with ineligible companies to disclose.



Learning Objectives

At completion of this activity, the participant will be able to:

- Discuss the latest changes in vaccine guidance for flu, COVID-19, pneumonia, and other vaccines.
- Assess implications of changes to vaccine guidance for pharmacy teams.



Regulatory Process

The Vaccine Life Cycle

safety at every phase

GUIDE

ACIP

ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES

BLA

BIOLOGICS LICENSE APPLICATION

CDC

CENTERS FOR DISEASE CONTROL AND PREVENTION

FDA

FOOD AND DRUG ADMINISTRATION

IND

INVESTIGATIONAL NEW DRUG APPLICATION

safety is a priority during vaccine development + approval

VACCINE DEVELOPMENT

PHASE 1 safety
PHASE 2 effectiveness
PHASE 3 safety + effectiveness

CLINICAL STUDIES / TRIALS

FDA REVIEW
ACIP REVIEW

FDA APPROVAL OF 1 NEW VACCINE
ACIP RECOMMENDATION

safety continues with CDC + FDA safety monitoring

PHASE 4
safety monitoring for serious, unexpected adverse events

POST-APPROVAL MONITORING + RESEARCH

BASIC RESEARCH
DISCOVERY
PRE-CLINICAL STUDIES

IND SUBMITTED

BLA SUBMITTED

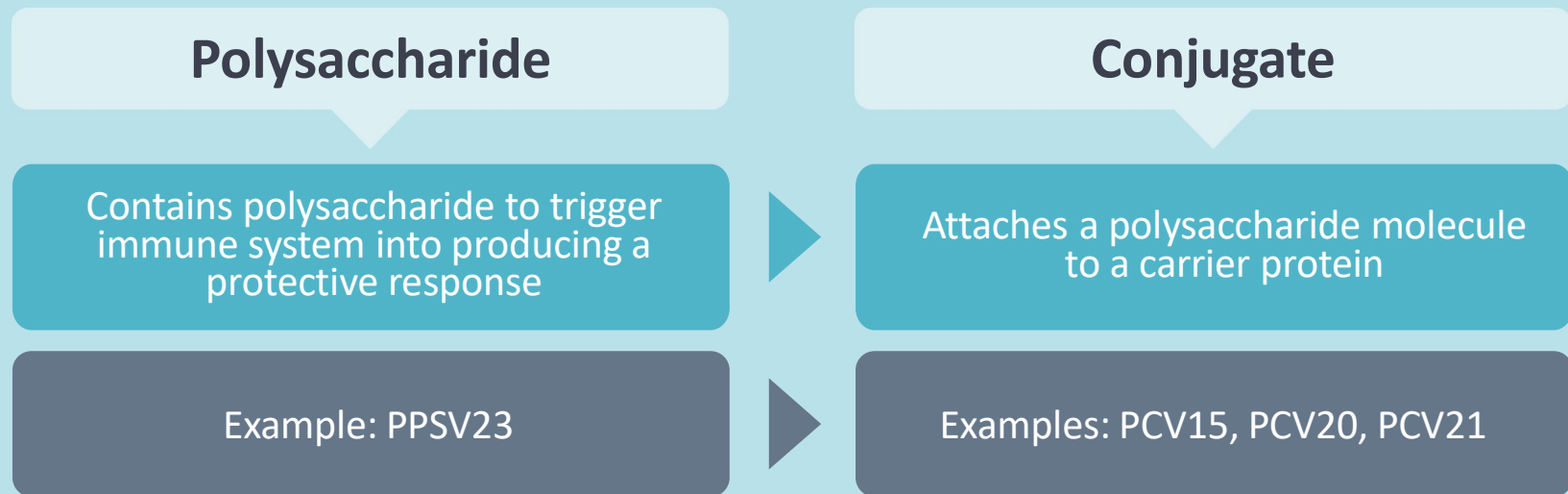
FDA APPROVAL OF 1 NEW VACCINE

ACIP RECOMMENDATION

Pneumococcal Vaccine

Bottom line up front: ACIP recommends a conjugate vaccine for a PCV-naïve adults aged 50 years and older

What is a conjugate vaccine?



What's the difference between available vaccines?

Serotypes	1	3	4	5	6 A	6 B	7 F	9 V	1 4	1 8 C	1 9 A	1 9 F	2 3 F	2 2 F	3 3 F	8	1 0 A	1 1 A	1 2 F	1 5 B	2	9 N	1 7 F	2 0	1 5 A	1 5 C	1 6 F	2 3 A	2 3 B	2 4 F	3 1	3 5 B						
PCV15																																						
PCV20																																						
PPSV23																																						
PCV21																																						

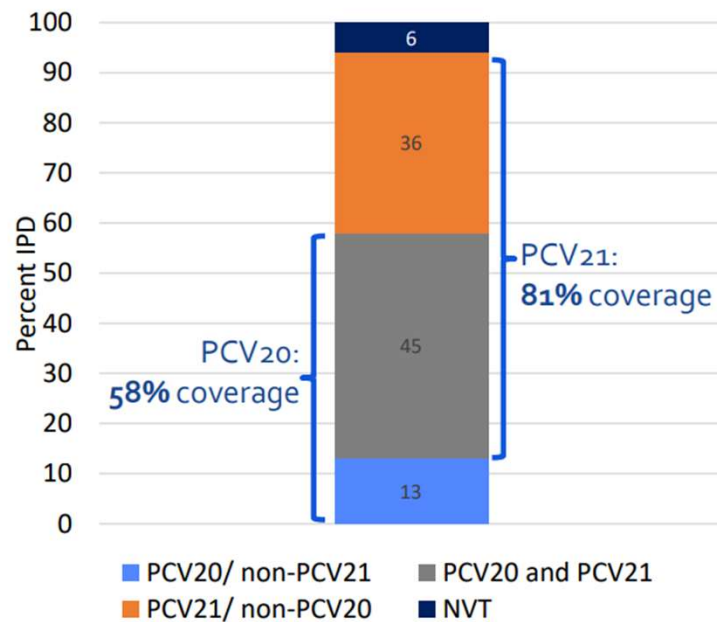
21-valent pneumococcal conjugate vaccine (CAPVAXIVE™, Merck):

- Approved by the FDA for adults aged ≥18 years on June 17, 2024¹

What's the difference between available vaccines?

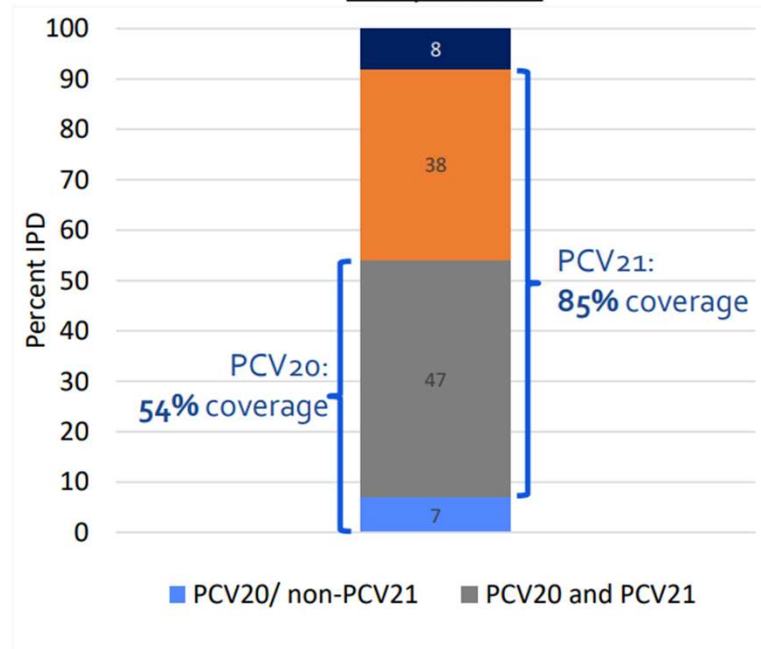
Proportion of IPD by vaccine-type among adults with a pneumococcal vaccine indication, 2018–2022

19-64 years old (with a risk-based indication)



PCV20/ non-PCV21 serotype: 1, 4, 5, 6B, 9V, 14, 18C, 19F, 23F, 15B
PCV20/ in-PCV21 serotypes: 3, 6A, 7F, 19A, 22F, 33F, 8, 10A, 11A, 12F, +6C
PCV21/ non-PCV20 serotypes: 9N, 17F, 20, 15A, 15C, 16F, 23A, 23B, 24F, 31, 35B

≥65 years old



[Gierke February 2024 ACIP meeting presentation](#)

Clinical Trial Data

Safety data:

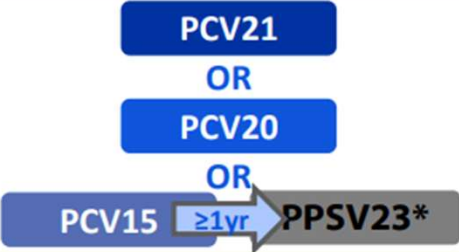
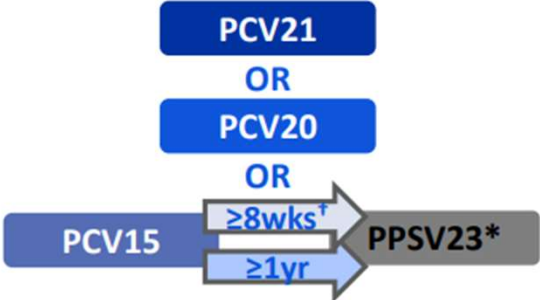
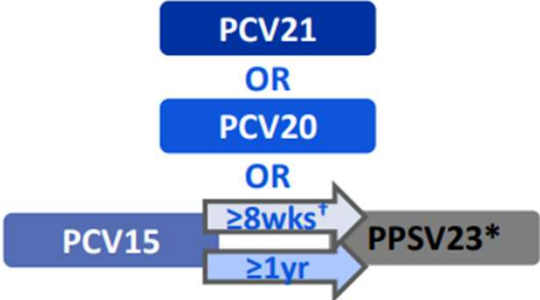
- no vaccine-related serious adverse events reported for PCV15 and 20
- 2 vaccine-related serious adverse events reported for PCV21

Immunogenicity data:

- PCV15 noninferior to PCV13 for all shared serotypes
- PCV20 noninferior to PCV13 for all shared serotypes
- PCV20 noninferior to PPSV23 for 6/7 shared serotypes
- PCV21 noninferior to PCV20 for 10/10 shared serotypes

Proposed Clinical Guidance

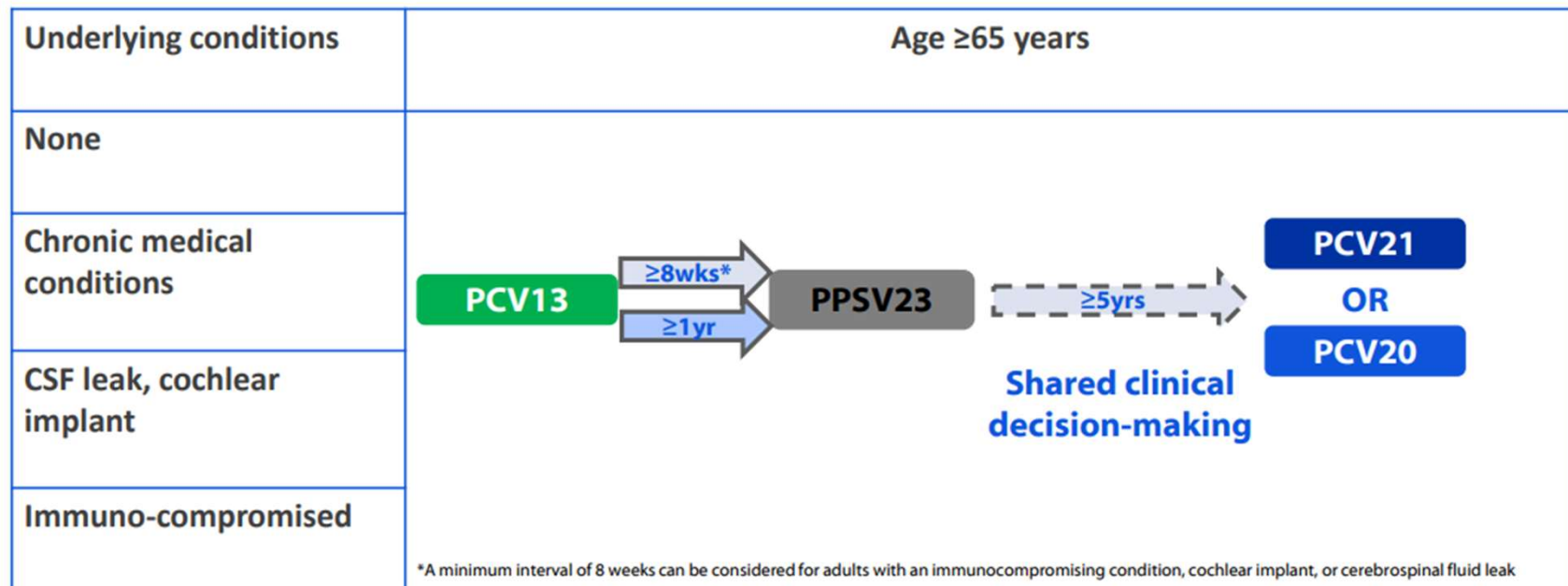
PCV-naïve adults (or adults with unknown history) **DRAFT**

Underlying conditions	Previous vaccination history	Age 19–49 years	Age ≥50 years
None	None	No vaccine recommendation	
Chronic medical conditions	None		
CSF leak, cochlear implant	None		
Immuno-compromised	None		

*If adults previously received PPSV23 before receiving a dose of PCV15, it need not be followed by another dose of PPSV23
 †A minimum interval of 8 weeks can be considered for adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak

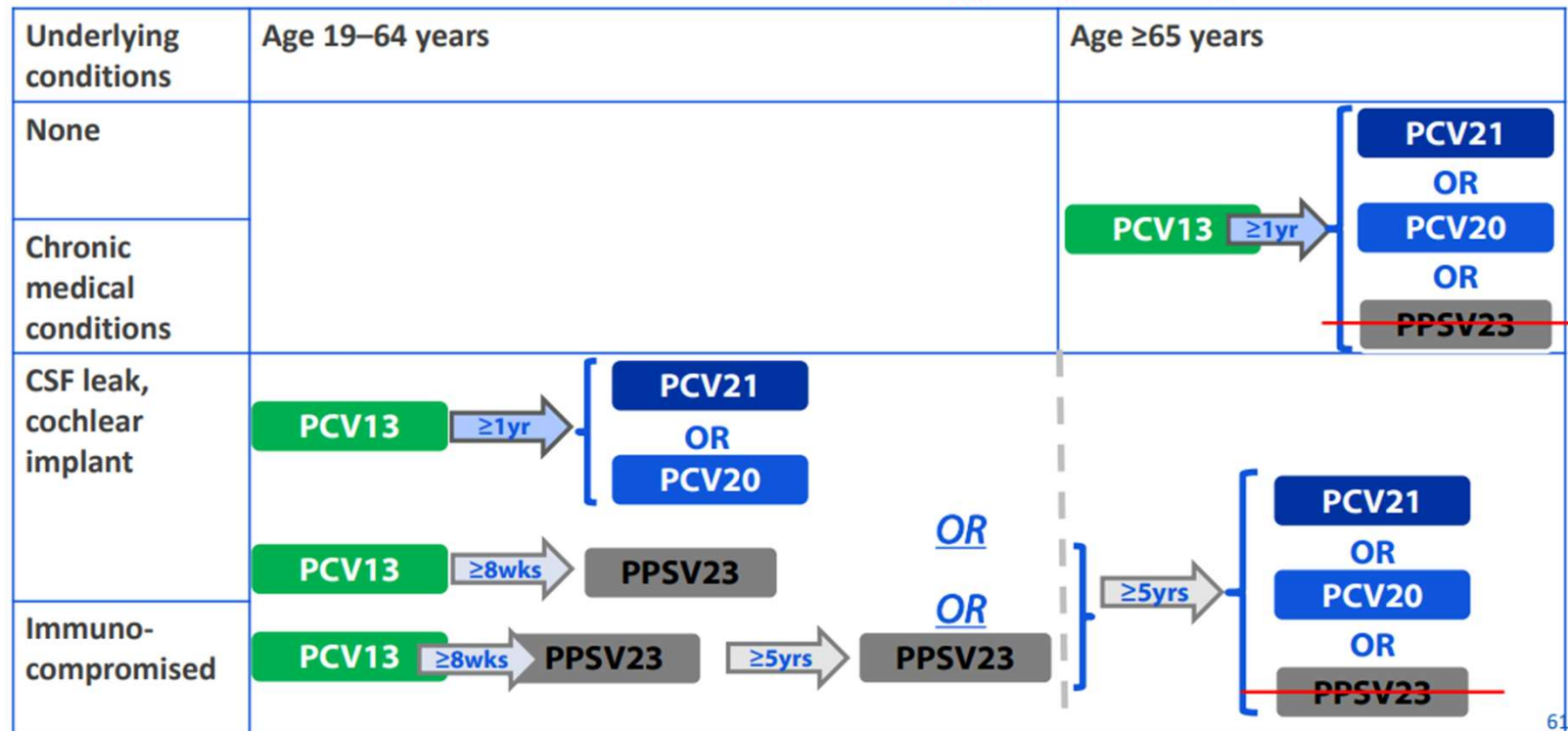
Proposed Clinical Guidance

PCV13-experienced adults who completed the recommended vaccine series **DRAFT (no change from current)**



Proposed Clinical Guidance

PCV13-experienced adults who have not completed the recommended vaccine series (proposed)



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What's Next?

New Adult Pneumococcal Vaccines in Advanced Stages of Development

	1	3	4	5	6	6	7	9	1	1	1	1	2	2	3	8	1	1	1	1	2	9	1	2	1	1	1	2	2	2	3	3	7		
					A	B	F	V	4	8	9	9	3	2	3		0	1	2	5		N	7	0	5	5	6	3	3	4	1	5	C		
PCV15																																			
PCV20																																			
PPSV23																																			
PCV21																																			
Pn-MAPS24v																																			
VAX-24																																			
VAX-31																																			

24-valent and 31-valent vaccines

Booster dose(s)

Removing polysaccharide vaccines

24-valent pneumococcal vaccines:

- Pn-MAPS24v (GSK): Completed phase 1/2 study for adults; Breakthrough Therapy Designation granted and next steps in preparation; undergoing phase 2 studies in infants¹
- VAX-24 (Vaxcyte): Completed enrollment for phase 2 studies in infants²; topline results anticipated in 2025

31-valent pneumococcal vaccine (VAX-31, Vaxcyte):

- Reported topline results of phase 1/2 study in adults aged ≥50 years³; plan to initiate phase 3 pivotal non-inferiority study by mid-2025
- Plans to initiate VAX-31 Infant Phase 2 Study in Q1 of 2025 following IND submission and clearance

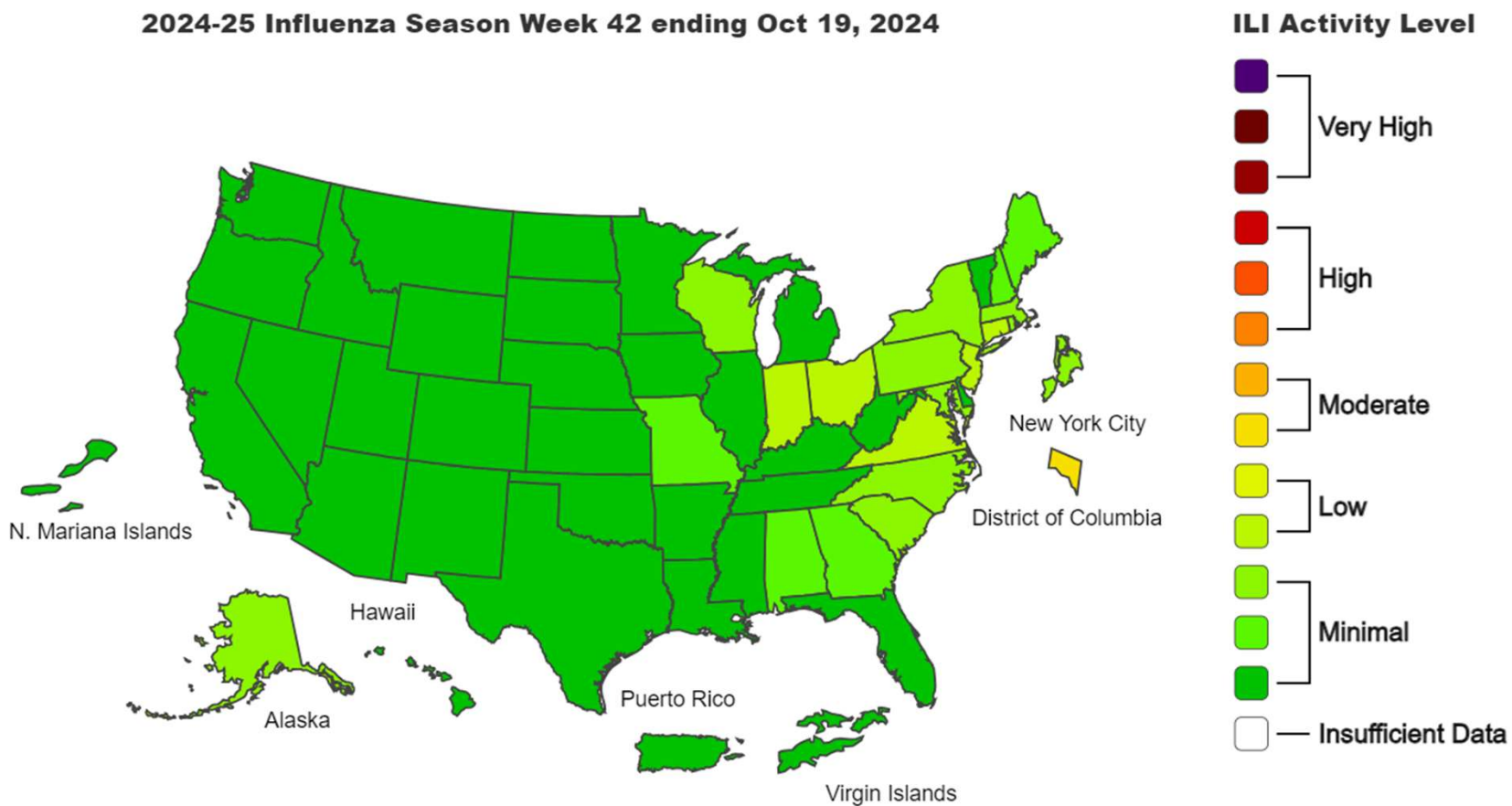
1. Chichili et al. Vaccine 2022; 2. Vaxcyte Completes Enrollment of Phase 2 Study Evaluating VAX-24 for the Prevention of Invasive Pneumococcal Disease (IPD) in Infants - Vaxcyte, Inc.; 3. VAX-31 Phase 1/2 Study Topline Results in Adults Aged 50 and Older, September 3, 2024

Influenza

Bottom line up front: 2024-25 flu vaccines remain recommended for everyone age 6 months and older

Weekly Flu Surveillance

2024-25 Influenza Season Week 42 ending Oct 19, 2024



Avian (Bird) Flu Update

A

- Can cause seasonal epidemics
- H1N1 and H3N2 infect humans
- **H5N1** infects animals (**bird flu**)

B

- Can cause seasonal epidemics
- B/Victoria and B/Yamagata lineages infect humans

C

Infects humans, usually children, and animals.

Mild and doesn't mutate often.

D

Infects animals; no known risk to humans

Avian (Bird) Flu Update

Human case summary during the 2024 outbreak, by state and exposure source

Exposure Source

State	Cattle	Poultry	Unknown	State Total
California	15	0	0	15
Colorado	1	9	0	10
Michigan	2	0	0	2
Missouri	0	0	1	1
Texas	1	0	0	1
Washington	0	5	0	5
Source Total	19	14	1	34

FluMist Update

FluMist is a live attenuated, trivalent influenza vaccine

- On 9/20/24, the FDA approved it for self or caregiver administration
- For this season, flu vaccines only available from a healthcare provider
- It is anticipated that in 2025-26 season, FluMist will be available for self or caregiver administration

What's Next?

Moderna Announces Positive Phase 3 Data for Combination Vaccine Against Influenza and COVID-19

June 10, 2024

Pfizer and BioNTech Provide Update on mRNA-based Combination Vaccine Program Against Influenza and COVID-19 in Individuals 18-64 Years of Age

Friday, August 16, 2024 - 06:45am

Oct 16, 2024

PRESS RELEASE

COVID-19

Update on Novavax's COVID-19-Influenza Combination and Stand-alone Influenza Phase 3 Trial

September 13, 2024

Combo COVID-19 and Flu mRNA Vaccine Falls Short of Total Flu Protection

Samantha Anderer

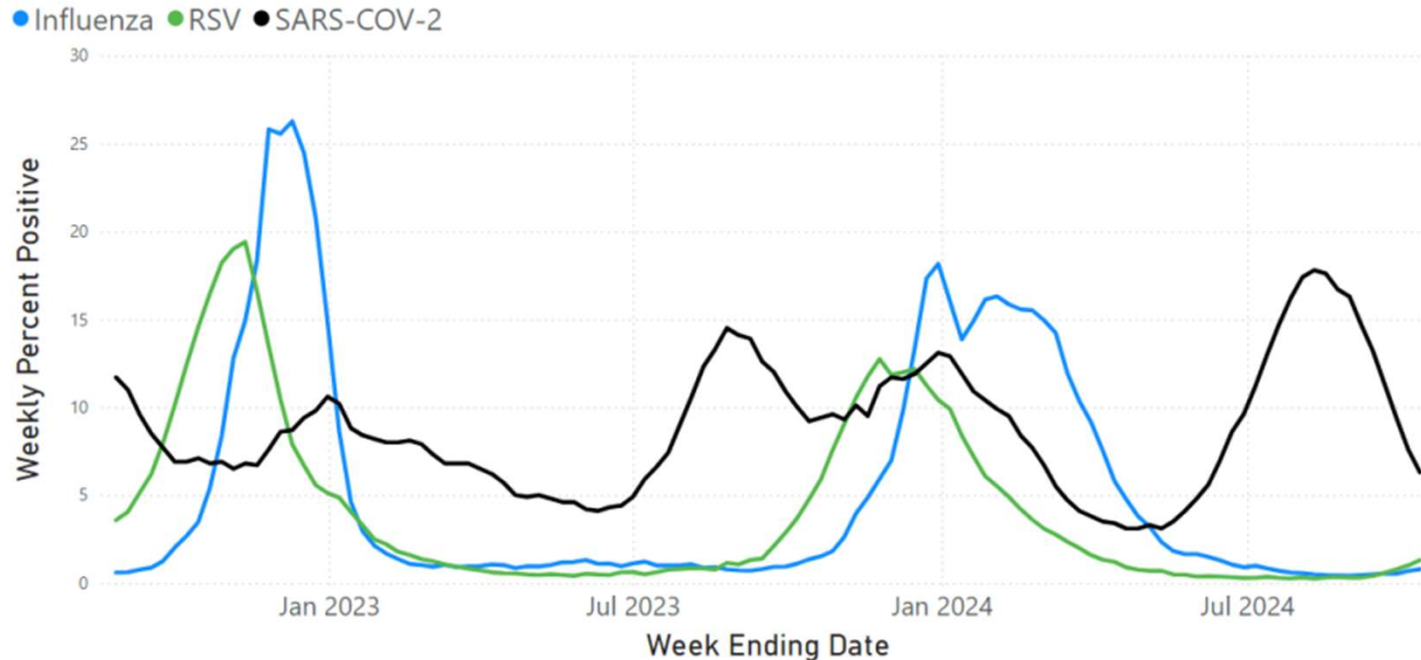
JAMA. 2024;332(14):1133. doi:10.1001/jama.2024.18194

COVID-19

Bottom line up front: ACIP now recommends a second dose of 2024-25 COVID-19 vaccine for people aged 65 years and older, and people aged 19-64 with a weakened immune system

COVID-19 circulates year-round.

National weekly percent positive for SARS-COV-2, RSV and influenza reported to NREVSS, August 27, 2022 through October 12, 2024



Reported was last updated on October 16, 2024.

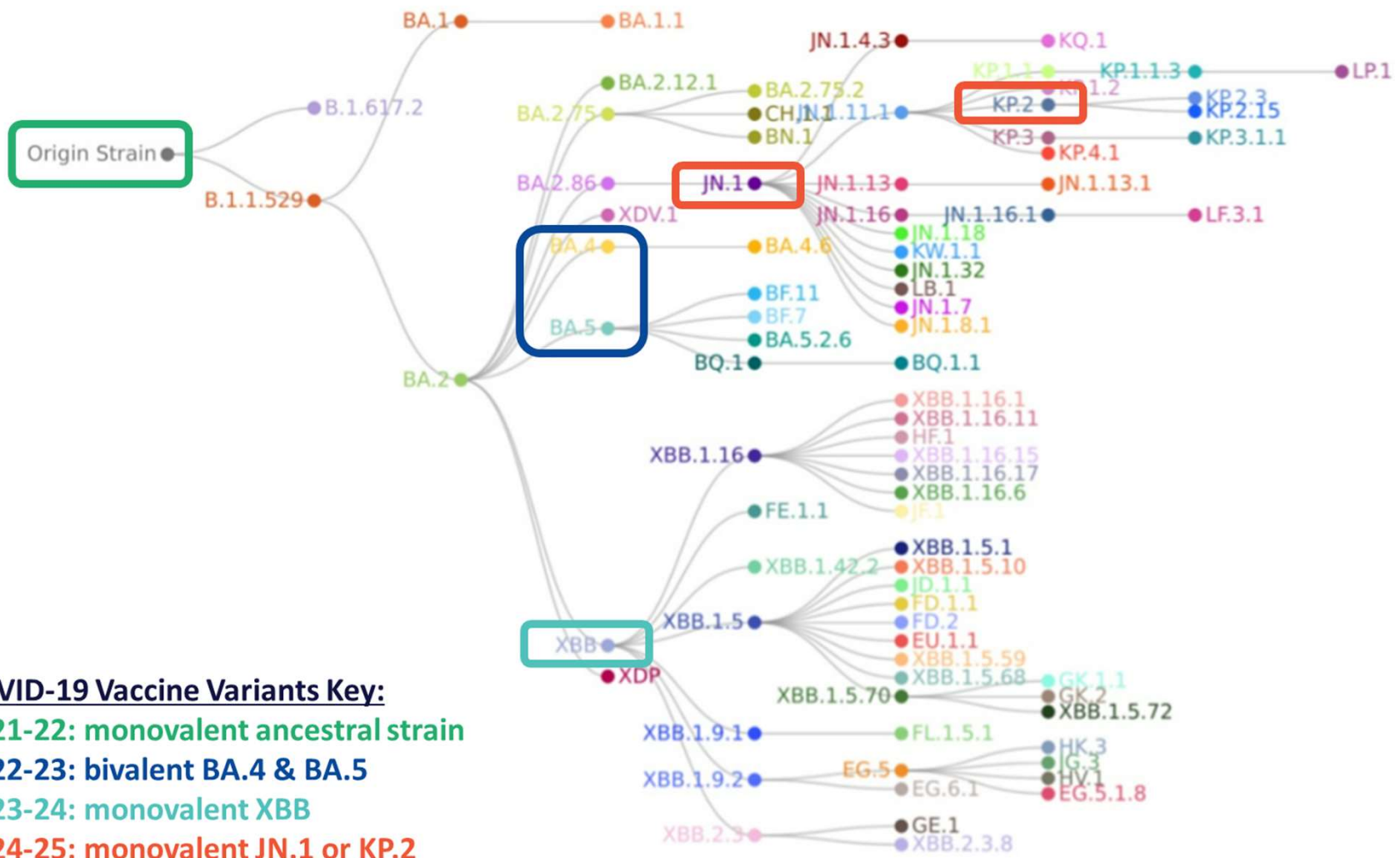
All results presented from nucleic acid amplification tests which represent >90% of the diagnostic tests reported to NREVSS. The last three weeks of data may be less complete. NREVSS is an abbreviation for the National Respiratory and Enteric Virus Surveillance System. For more information on NREVSS, please visit www.cdc.gov/surveillance/nrevss.

SARS-COV-2: Severe acute respiratory syndromic coronavirus type 2

Flu: Influenza viruses types are combined but reported by type and subtype depending on the testing capabilities of each contributing laboratory.

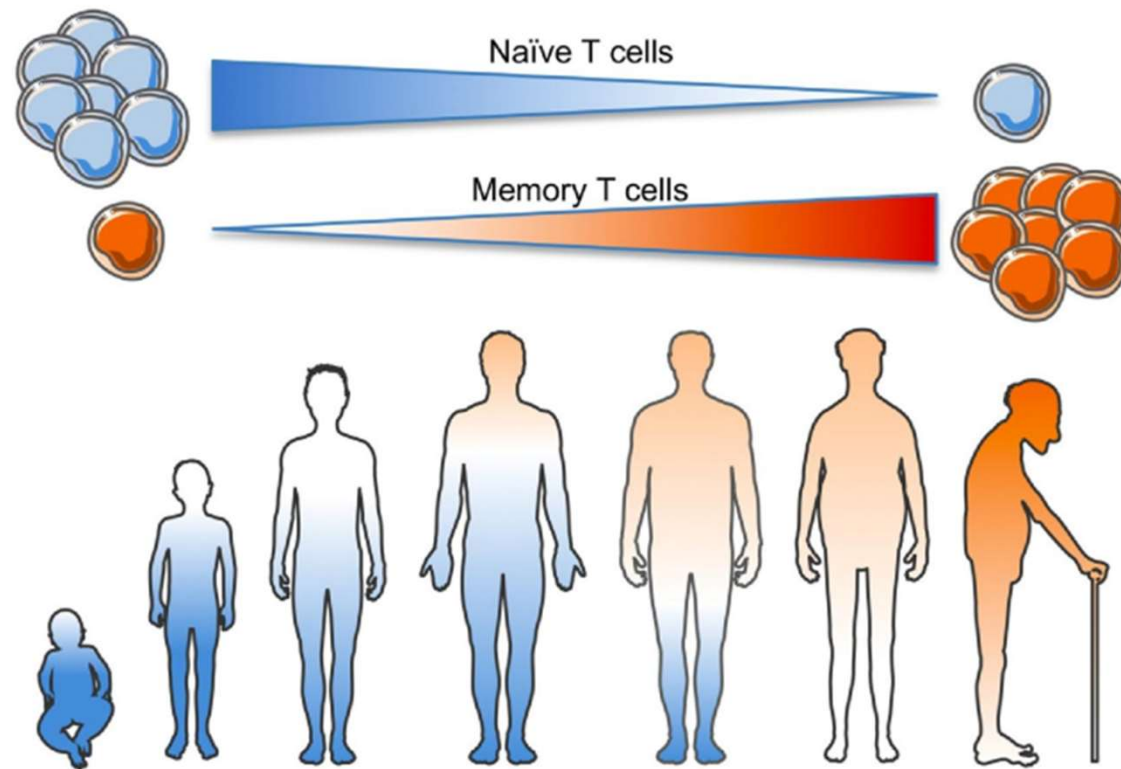
RSV: Respiratory Syncytial Virus. Types A and B are reported but not shown separately in this report.

<https://www.cdc.gov/nrevss/php/dashboard/index.html>



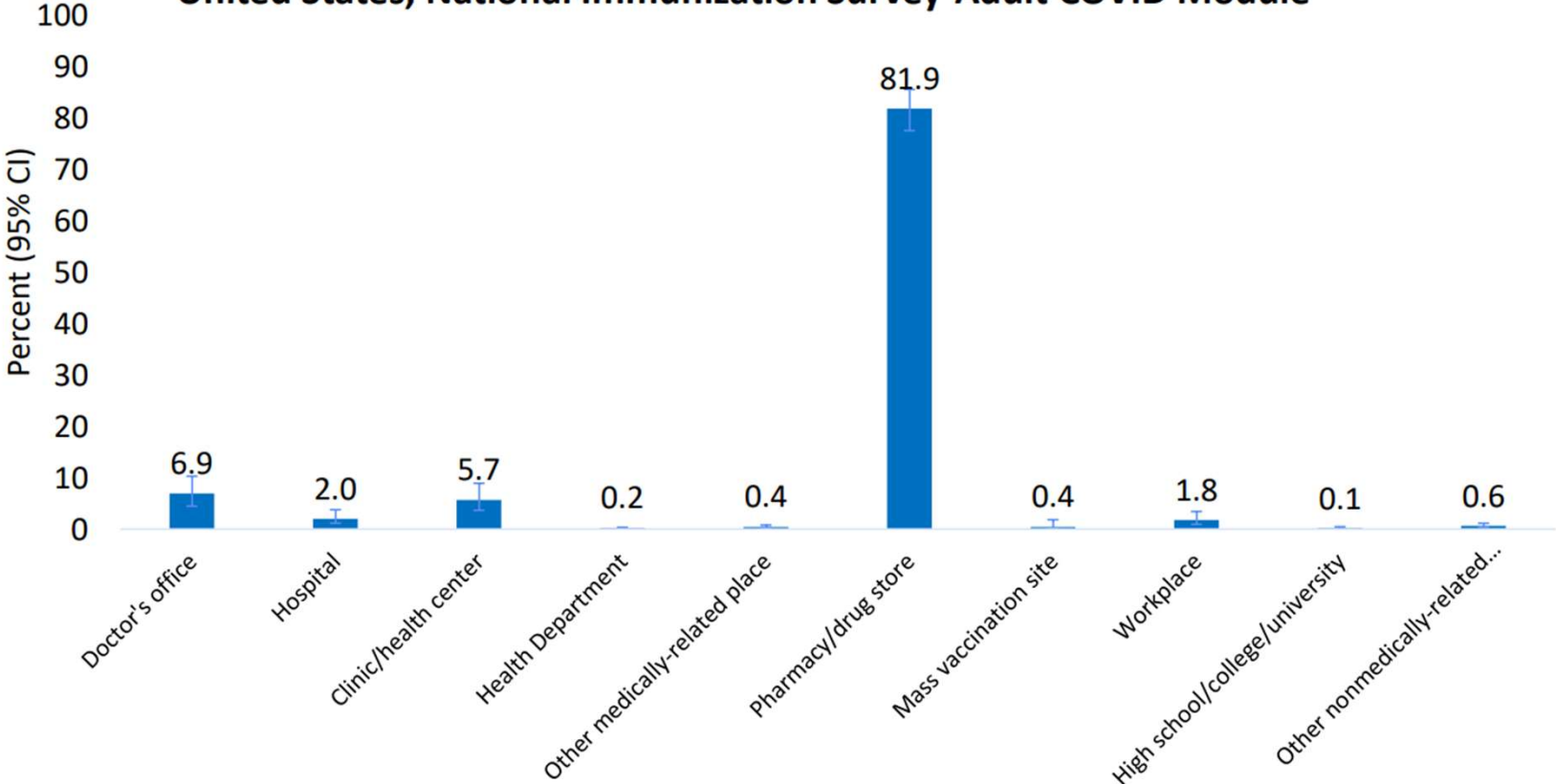
COVID-19 Vaccine Variants Key:
 2021-22: monovalent ancestral strain
 2022-23: bivalent BA.4 & BA.5
 2023-24: monovalent XBB
 2024-25: monovalent JN.1 or KP.2

Why recommend a second dose?



Place of 2024-2025 COVID-19 Vaccination

Reported place of updated COVID-19 vaccination, adults aged ≥18 years, United States, National Immunization Survey-Adult COVID Module*



*Among persons who reported receiving an updated 2024-2025 COVID-19 vaccination since August 22, 2024 (n=2,943). Data collected September 1-28, 2024.

Routine vaccination

Children ages 6 months–4 years

- Unvaccinated: Should receive a multidose initial series with a 2024–2025 mRNA vaccine
- Previously completed an initial series: Should receive 1 dose of a 2024–2025 mRNA vaccine from the same manufacturer as the initial series

People ages 5–64 years:

- Should receive 1 dose of an age-appropriate 2024-2025 COVID-19 vaccine*

People ages 65 years and older:

- Should receive 2 doses of any 2024–2025 COVID-19 vaccine, spaced 6 months apart

Immunocompromised

Initial vaccination:

- Should receive a multidose vaccination series with an age-appropriate 2024–2025 vaccine and receive 1 2024–2025 dose 6 months after completing the initial series

Previously completed an initial series:

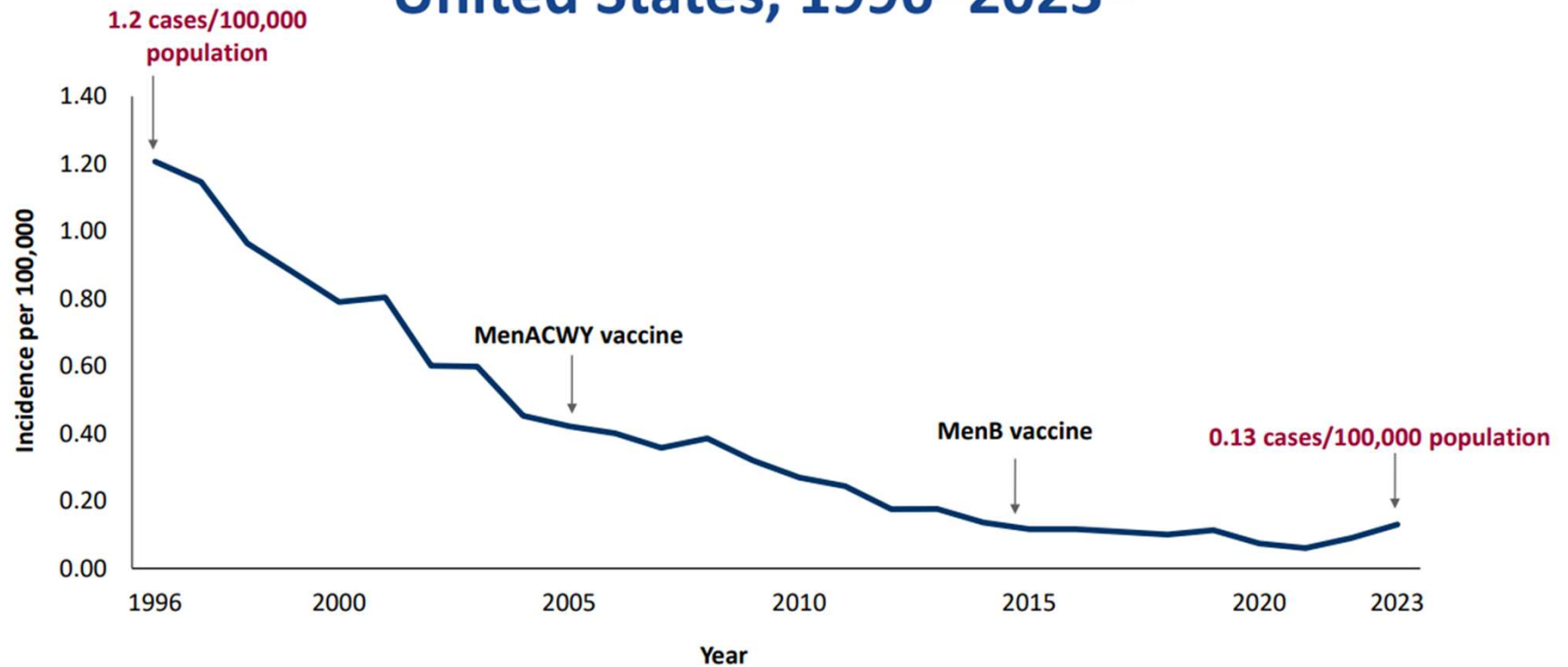
- Should receive 2 doses of an age-appropriate COVID-19 2024–2025 vaccine, spaced 6 months apart

May receive additional age-appropriate 2024–25 COVID-19 vaccine doses under shared clinical decision-making.

Meningococcal

Bottom line up front: Bexsero (meningitis B vaccine) dose schedule now harmonizes with Trumenba dose schedule.

Meningococcal Disease Incidence – United States, 1996–2023*



Abbreviations: MenACWY vaccine = quadrivalent (serogroups A, C, W, and Y) meningococcal conjugate vaccine; MenB vaccine = serogroup B meningococcal vaccine
Source: 1996–2023 NNDSS Data. *2023 NNDSS data are preliminary.

Meningitis B Vaccines

Routine schedule of Bexsero vs. Trumenba:

- *Bexsero*: 2 dose series at 0 and at least 1 month → now updated to 0 and 6 months
- *Trumenba*: 2 dose series at 0 and 6 months

Higher risk schedule due to asplenia, during outbreak, etc.:

- *Bexsero*: 2 dose series at 0 and at least 1 month → now updated to 0, 1-2, and 6 months
- *Trumenba*: 3 dose series at 0, 1-2, and 6 months

Pfizer and GSK MenABCWY Vaccines

	Pfizer (Penbraya)	GSK*
ACWY component	Nimenrix (not licensed in U.S.)	Menveo
B component	Trumenba	Bexsero
Schedule	2 doses, 6 months apart	2 doses, 6 months apart*
Age	10–25 years	10–25 years*

*Vaccine not yet licensed in U.S. and this slide represents anticipated schedule and age indications

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What's next?

- Revisiting the adolescent meningococcal vaccine schedule to include pentavalent meningitis vaccines at a 2025 ACIP Meeting

Chikungunya

Bottom line up front: the workgroup is considering a virus-like particle vaccine submitted to FDA for licensure.

Chikungunya Vaccines

A virus-like particle vaccine will provide an option for people aged 12+ years.
The live virus is available for people aged 18+ years.

What's next?

- Need for booster dose currently unknown
- Additional safety and effectiveness data to be collected
- The Work Group will review and present policy for a vote at a future meeting

RSV

Bottom line up front: no changes to recommendations yet, but consideration is ongoing for adult age expansion and pediatric options.

Available RSV Vaccines

Protein subunit:

- *GSK Arexvy, adjuvanted*
 - [ACIP-approved](#) for adults aged 60+; [FDA-approved](#) for 50+
- *Pfizer Abrysvo, no adjuvant*
 - [ACIP-approved](#) for adults aged 60+ and pregnant people; [FDA-approved](#) for 18+

mRNA:

- *Moderna mResvia, no adjuvant:*
 - [ACIP-approved](#) for adults aged 60+

Given the considerable benefits and evidence of safety, the Work Group continues to feel coadministration is acceptable

While uncertainty remains in the magnitude of GBS risk associated with protein subunit RSV vaccination, the Work Group continues to believe benefits outweigh risks

Maternal/Pediatric RSV Updates

MAB options for infants:

- Nirsevimab has a longer half-life than Clesrovimab (71 days vs. 42), however efficacy against severe RSV appeared sustained at 180 and 150 days, respectively)

Pre-term births and hypertensive disorders in maternal RSV vaccine recipients:

- Differences vs. placebo were not statistically significant and data were insufficient to establish or exclude a causal relationship
- ACIP again judged the benefits of maternal RSV vaccine to outweigh potential risks

What's next?

- ACIP could vote on clesrovimab as early as February 2025 (depends on FDA licensure)

HPV

Bottom line up front: evidence is accumulating on efficacy of HPV vaccination with fewer doses and beginning at a younger age.

Current HPV vaccination recommendations, United States

Routine vaccination

- Age 11 or 12 years
- Can be started at age 9 years

Catch-up vaccination

- Through age 26 years

Shared clinical decision-making

- Age 27–45 years

Number of doses

2 doses (0, 6-12 months)
if starting series before 15th birthday

3 doses (0,1-2, 6 months)
if starting series on or after 15th birthday or
if immunocompromising condition

What's next?

-Workgroup plans to share additional data, modeling, and partial evidence to recommendations at February 2025 ACIP meeting in support of beginning the series at age 9 instead of 11. A vote won't be earlier than June 2025.

CMV

Bottom line up front: a mRNA vaccine candidate is expecting results next year, so a workgroup is being formed in preparation.

New Workgroup for cytomegalovirus

CMV is a common virus that infects people of all ages.

- In the United States, nearly 1 in 3 children is already infected with CMV by age 5.
- Over half of adults have been infected with CMV by age 40.

To date, no licensed vaccine, however, mRNA candidate has results expected next year.

What's next?

- At February ACIP meeting, workgroup will review burden of CMV

MPox

Bottom line up front: There is an Mpox outbreak in DRC, but risk is considered very low for U.S. travelers and the general U.S. population.

Mpox Update

What's next?

- Workgroup considering bringing to an ACIP vote, use of JYNNEOS in persons 12-17 years of age at risk during mpox outbreaks
- Planning publication of ACIP recommendations in MMWR for persons 12+

Immunization Schedules

Bottom line up front: 2025 U.S. immunization schedules are approved

2025 Updates

- Harmonizes the child/adolescent and adult schedules
- Updates changes in guidance
- VFC schedule changes have been implemented to match

Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger

UNITED STATES
2025

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

Immunological activity	Abbreviation(s)	Trade name(s)
Respiratory (nasal/intranasal) antibody (mucosal)	IPVnasal	Surflin [®]
Vaccine	Abbreviation(s)	Trade name(s)
COVID-19	1vCOVID-19 mRNA	Comirnaty [®] /Pfizer BioNTech COVID-19 Vaccine
	1vCOVID-19 PS	Spikevax [™] /Moderna COVID-19 Vaccine
Dengue vaccine	1vDENV-4	Qdenga [®]
Diphtheria, tetanus, and acellular pertussis vaccine	DTaP	Acelfor [®]
Haemophilus influenzae type b vaccine	Hib (IPV-E)	ActHib [®]
	sub-unit (non-IPV)	Hibix [®]

How to use the child and adolescent immunization schedule

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

Recommended by the Advisory Committee on Immunization Practices (www.cdc.gov/vaccines/imz/advis)

Recommended Adult Immunization Schedule for ages 19 years or older

UNITED STATES
2025

Vaccines in the Adult Immunization Schedule*

Vaccine	Abbreviation(s)	Trade name(s)
COVID-19 vaccine	1vCOVID-19 mRNA	Comirnaty [®] /Pfizer-BioNTech COVID-19 Vaccine
	1vCOVID-19 PS	Spikevax [™] /Moderna COVID-19 Vaccine
Adenoviral influenza type b vaccine	Hib	ActHib, Hibiterix, Pedvax-HB
Hepatitis A vaccine	HepA	Harvix, Vagta
Hepatitis A and hepatitis B vaccine	HepA-HepB	Twinrix
Hepatitis B vaccine	HepB	Engerix-B, HepBvac-B, ProHepBrio, Recombivax HB
Human papillomavirus vaccine	HPV	Gardasil 9
Influenza vaccine (inactivated, egg-based)	IN3	Fluzel
Influenza vaccine (inactivated, cell-culture)	HD-IN3	Fluzone High-Dose
Influenza vaccine (recombinant)	IN3	Flucelvax
Influenza vaccine (live, attenuated)	LAN3	FluMist
Mumps, measles, and rubella vaccine	MMR	M-M-R-II, Priorix
Meningococcal serogroup A, C, W, Y vaccine	MenACWY-CRM	Menveo
	MenACWY-TT	MenQuadfi
Meningococcal serogroup B vaccine	MenB-4C	Bexsero
	MenB-FHbp	Trumenb
Meningococcal serogroup A, B, C, W, Y vaccine	MenACWY-TV	Penbrava
Mpox vaccine	Mpox	Jynneos
Pneumococcal conjugate vaccine	PCV15	Varenance
	PCV20	Pneum 20
	PCV21	Capniae
Pneumococcal polysaccharide vaccine	PPSV23	Pneumovax 23
Poliovirus vaccine	IPV	Ipov
Respiratory syncytial virus vaccine	RSV	Abraxis, Arexxy, mResvia
Tetanus and diphtheria vaccine	Td	Tenivac
Tetanus, diphtheria, and acellular pertussis vaccine	Tdap	Adacel, Boostrix
Varicella vaccine	VAR	Varivax
Zoster vaccine, recombinant	RZV	Shingrix

*Administer recommended vaccine 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 ACP or CDC.

How to use the adult immunization schedule

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

Recommended by the Advisory Committee on Immunization Practices (www.cdc.gov/vaccines/imz/advis) 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 Assistants (www.aapa.org), American Pharmacists Association (www.pharmacist.org), and Society for Healthcare Epidemiology of America (www.shsa-online.org).

Report

- Suspected cases of reportable vaccine-preventable diseases or outbreaks to the local or state health department
- Clinically significant adverse events to the Vaccine Adverse Event Reporting System at [www.vaers.fda.gov](https://vaers.fda.gov) or 800-822-7967

Questions or comments

Contact www.cdc.gov/ncidod/diseases/zoonotic/dx/2019-nCoV or 800-CDC-INFO (800-232-4636), 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/imz/advis
- ACP Shared Clinical Decision-Making Recommendations: www.acponline.org/clinical-decision-making
- General Best Practice Guidelines for Immunization: www.cdc.gov/vaccines/imz/advis/guidelines
- Vaccine information statements: www.cdc.gov/vaccines/imz/advis/vi
- Manual for the Surveillance of Vaccine-Preventable Diseases (including case identification and outbreak response): www.cdc.gov/vaccines/imz/advis/surv-manual



References



- [How Vaccines are Developed and Approved for Use | Vaccines & Immunizations | CDC](#)
- [ACIP Presentation Slides: October 23-24, 2024 Meeting | ACIP | CDC](#)
- [About Pneumonia | Pneumonia | CDC](#)
- [Weekly US Influenza Surveillance Report: Key Updates for Week 42, ending October 19, 2024 | FluView | CDC](#)
- [H5 Bird Flu: Current Situation | Bird Flu | CDC](#)
- [Update on Novavax's COVID-19-Influenza Combination and Stand-alone Influenza Phase 3 Trial - Oct 16, 2024](#)
- [About Cytomegalovirus | Cytomegalovirus \(CMV\) and Congenital CMV Infection | CDC](#)
- [CDC Recommends Lowering the Age for Pneumococcal Vaccination from 65 to 50 Years Old | CDC Newsroom](#)
- [CDC Recommends Second Dose of 2024-2025 COVID-19 Vaccine for People 65 Years and Older and for People Who are Moderately or Severely Immunocompromised | CDC Newsroom](#)



Contact Info

Olivia Kinney, PharmD, MS
olivia.kinney@kroger.com



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