Implementing ACIP Recommendations this Fall

Lori Handy, MD, MSCE

Division of Infectious Diseases

Associate Director, Vaccine Education Center

The Children's Hospital of Philadelphia

Perelman School of Medicine

University of Pennsylvania

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Children's Hospital of Philadelphia®

Overview

- Nirsevimab
- RSV maternal vaccine
- RSV Adult vaccines
- COVID-19 vaccines
- Influenza vaccines: Routine and High dose recommendations
- Pneumococcal vaccines

Data credit: June ACIP meeting
https://www.cdc.gov/vaccines/acip/meetings/slides-2024-06-26-28.html. Accessed 8/29/2024

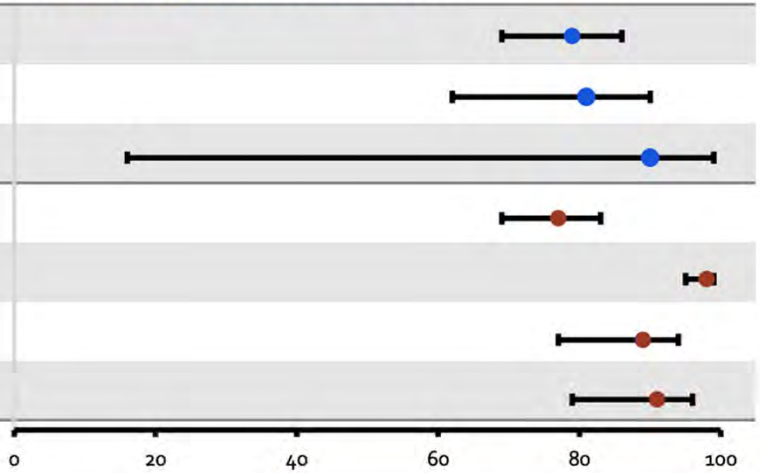
Nirsevimab

Effectiveness

- Efficacy – reported in clinical trials as the degree to which immunization is protective in ideal and controlled conditions
- Effectiveness - reported in post marketing (Phase 4) studies as the degree to which immunization is protective in real world conditions
- Good news here!

Observational data indicate nirsevimab is working as expected (vs. RCT results) during the first RSV season after approval among infants in their first RSV season

Outcome/Analysis	Vaccine efficacy/effectiveness (%)
Clinical trial, RSV-associated LRTI	79 (69-86)
Clinical trial, RSV-associated LTRI with hospitalization	81 (62-90)
Clinical trial, RSV-associated LRTI with ICU admission	90 (16-99)
VISION, RSV-associated emergency department visits	77 (69-83)
VISION, RSV-associated hospitalization	98 (95-99)
NVSN, medically attended RSV-associated ARI episode	89 (77-94)
NVSN, RSV-associated hospitalization	91 (79-96)



Results may not be comparable across studies due to differences in outcome definitions, timing, and other factors.

https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm

RCT = randomized clinical trial | ARI = acute respiratory illness

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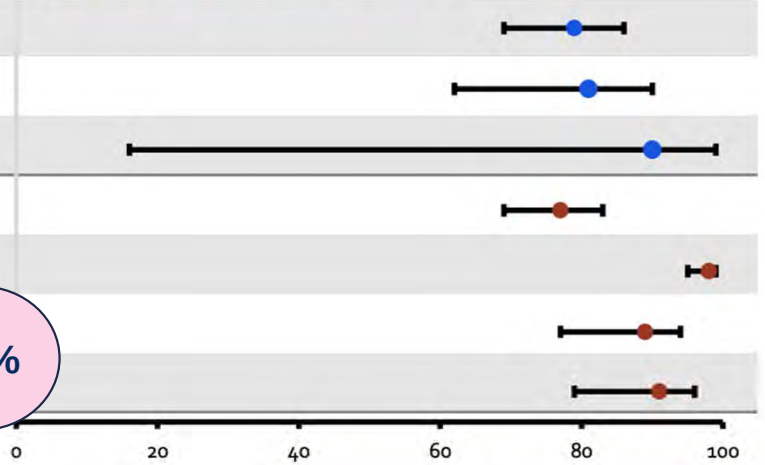

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Empirical studies* on nirsevimab product effectiveness (PE) among infants in their first RSV season

Citation	Country	Sample Size (Number of Infants)	Study Design	PE (95% Confidence Interval)
Ares-Gomez et al., 2024	Spain	10,259	Prospective Cohort	Hospitalization for RSV-related LRTI: 82% (95% CI: 66% - 90%) Severe RSV-related LRTI requiring oxygen support: 87% (95% CI: 69% - 94%) All-cause LRTI hospitalizations: 69% (56% - 78%) All-cause hospitalizations: 66% (56% - 74%)
Coma et al., 2024	Spain	26,525	Retrospective Cohort	Hospital admission for RSV-related disease: 88% (95% CI: 82% - 91%) Hospital ER visits due to bronchiolitis: 55% (95% CI: 48% - 62%) Medically attended RSV infection: 69% (95% CI: 52% - 80%) Primary care attended bronchiolitis: 48% (95% CI: 42% - 53%) Viral pneumonia diagnosed in primary care: 61% (95% CI: 24% - 80%) ICU admission for RSV-related disease: 90% (95% CI: 76%- 96%)
Estrella-Porter et al., 2024	Spain	27,362	Retrospective Cohort	Medically attended RSV infection: 74% (95% CI: 65% - 80%)
Ezpeleta et al., 2024	Spain	1,177	Prospective Cohort	Hospitalization due to RSV: 89% (95% CI: 70% - 96%) RSV infection attended in the ER: 88% (95% CI: 70% - 95%) RSV ICU admission: 86% (95% CI: 13% - 98%)
Lopez-Lacort et al., 2024	Spain	166	Screening and Test negative case control	RSV-LRTI hospital admission (pooled data across several regions): Screening methods: 84% (95% CI: 77% - 90%) Test negative design: 70% (95% CI: 38% - 89%)
Paireau et al., 2024	France	288	Test negative case control	RSV bronchiolitis hospitalized In the pediatric ICU: 76% (95% CI: 49% - 89%)
Aguera et al., 2024	Spain	181	Test negative case control	Hospitalization for RSV-related LRTI: 81% (95% CI: 61% - 91%) Severe RSV-related LRTI requiring NIV/CMV: 86% (95% CI: 42% - 96%)

*Published during June 20, 2023, through June 21, 2024

LRTI = lower respiratory tract infection | ER = emergency room | ICU = intensive care unit | CI = confidence interval | NIV: noninvasive ventilation | CMV: continuous mandatory ventilation

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82%

88%

89%

84%

81%

*Published during June 20, 2023, through June 21, 2024

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Fall Implementation

- Manufacturer supply – increased volume compared to 23-24
- Available in Sep, increasing through early October
- Availability increases confidence in program implementation
- Promote immunization NOW
- Local supply will be driven by ordering of different providers
  - Local collaboration essential to have sufficient coverage

Fall Implementation

- Covered by VFC
  - Birthing hospital coverage increasing but far from complete
- Covered by Medicaid, most private insurers
- Provide even after a documented RSV infection
- Safe to co-administer with other vaccines

Maternal RSV Vaccine

Safety: Is the RSV vaccine associated with preterm birth?

MMWR Morbidity and Mortality Weekly Report

MMWR Morb Mortal Wkly Rep. 2023 Oct 13; 72(41): 1115–1122.
Published online 2023 Oct 13. doi: 10.15585/mmwr.mm7241e1

PMCID: PMC10578951
PMID: 37824423

Use of the Pfizer Respiratory Syncytial Virus Vaccine During Pregnancy for the Prevention of Respiratory Syncytial Virus–Associated Lower Respiratory Tract Disease in Infants: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023

In clinical trials among pregnant persons at 24–36 weeks' gestation, more preterm births (<37 weeks' gestation) were observed among RSVpreF vaccine recipients than placebo recipients, although the differences were not statistically significant (1,2). Available data were insufficient to establish or exclude a causal relationship between preterm birth and RSVpreF vaccine. FDA labeled the potential risk for preterm birth as a warning and approved RSVpreF vaccine for use in pregnant persons at 32–36 weeks' gestation to avoid the potential risk for preterm birth at <32 weeks' gestation, which is associated with increased risk for morbidity and mortality (2). More hypertensive disorders of pregnancy were observed among RSVpreF

Safety: Is the RSV vaccine associated with preterm birth?

RSV Prefusion F Protein–Based Maternal Vaccine — Preterm Birth and Other Outcomes

Authors: Ilse Dieussaert, I.R., Joon Hyung Kim, M.D., Sabine Luik, M.D., Claudia Seidl, M.Sc., Wenji Pu, Ph.D., Jens-Ulrich Stegmann, M.D., Geeta K. Swamy, M.D., Peggy Webster, M.D., and Philip R. Dormitzer, M.D., Ph.D. Author Info & Affiliations

Published March 13, 2024 | N Engl J Med 2024;390:1009-1021 | DOI: 10.1056/NEJMoa2305478 | VOL. 390 NO. 11

The primary outcomes were any or severe medically assessed RSV-associated lower respiratory tract disease in infants from birth to 6 months of age and safety in infants from birth to 12 months of age. After the observation of a higher risk of preterm birth in the vaccine group than in the placebo group, enrollment and vaccination were stopped early, and exploratory analyses of the safety signal of preterm birth were performed.

Post-licensure surveillance

- VAERS: Preterm delivery events – 37
  - Can detect events, cannot detect causality
- VSD: Preterm delivery 4.1% (Population expected 3.1-6.1%)

VAERS Data

Preterm deliveries (as of June 3, 2024)

Classification[1]	N
Late preterm (34-36 weeks)	27
Early preterm (≥ 32 - <34 weeks)	7
Very preterm (28 - < 32 weeks)	0
Extremely preterm (< 28 weeks)	0
Unknown gestational age	3
Total	37**

[1] Based on ACOG and WHO definitions

Risk factors and clinical information[2]

- 22 reported a medical condition or complication that increased risk for preterm delivery (e.g., elevated blood pressure, history of preterm delivery)
- 12 had insufficient information (no medical records)
- 3 uncomplicated pregnancies (no reported factors)
- 8 deliveries were induced

[2] Median maternal age at vaccination was 33 years (range 25-40 years); median onset interval from vaccination to preterm birth was 3 days (range 0-31 days)

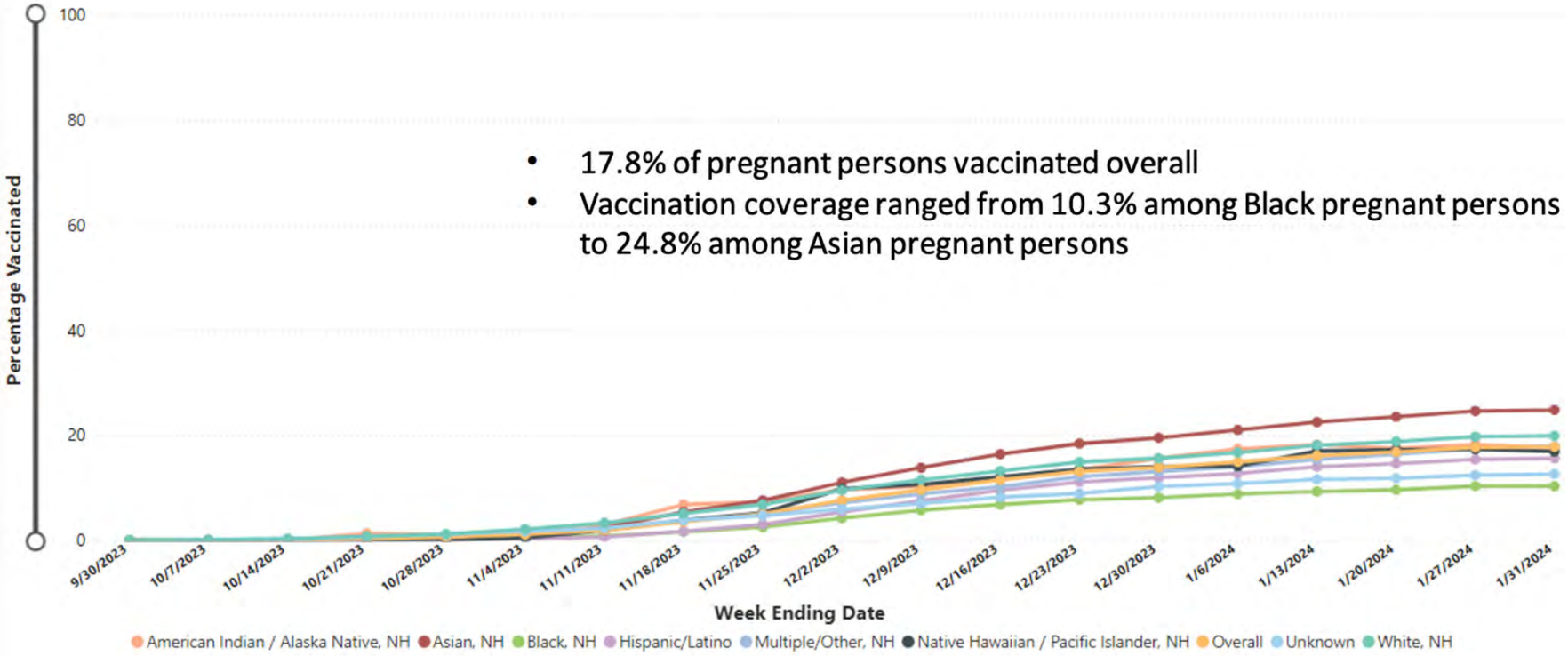
From October 2023 through March 2024, an estimated 320,400 pregnant persons received RSV vaccine (Peacock. Implementation and Uptake of Nirsevimab and Maternal RSV Vaccine. Advisory Committee on Immunization Practices. June 28, 2024.

Safety takeaways

- Local and systemic symptoms reported to V-safe similar to trials
- VAERS reports with no unexpected adverse events
- Preliminary findings from VSD
  - Preterm births within expected range of pregnant people
  - Full analysis to follow
  - Use later in pregnancy mitigated preterm birth, if truly associated
- CDC/FDA will continue to monitor VAERS, V-safe, VSD

Implementation

Percent of pregnant persons ages 18–49 years vaccinated with RSV vaccine overall and by race and ethnicity, Vaccine Safety Datalink



- 17.8% of pregnant persons vaccinated overall
- Vaccination coverage ranged from 10.3% among Black pregnant persons to 24.8% among Asian pregnant persons

Data source: https://www.cdc.gov/vaccines/imz-managers/coverage/rsvvaxview/pregnant-persons-coverage-intent.html

Fall Implementation

- Available now!
- No supply/demand mismatch
- Ensure awareness throughout your practice
- Beginning discussing/promoting vaccination with all pregnant patients
- Continue to be challenged to link maternal/infant health record
- **Strong recommendation from OB provider critical**
  - Location flexible: medical office, pharmacy, health center
- Revaccination in subsequent pregnancy not currently recommended

Maternal/Pediatric Respiratory Syncytial Virus (RSV) Work Group

Sarah S. Long, MD
Chair, Maternal/Pediatric RSV Work Group

ACIP Meeting

June 28, 2024

Fall Implementation

Timing of RSV vaccine and nirsevimab

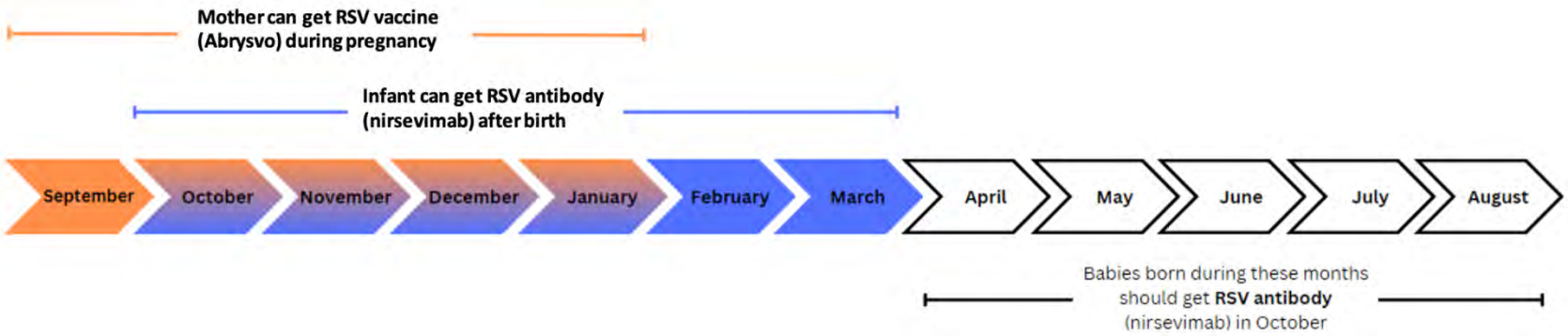
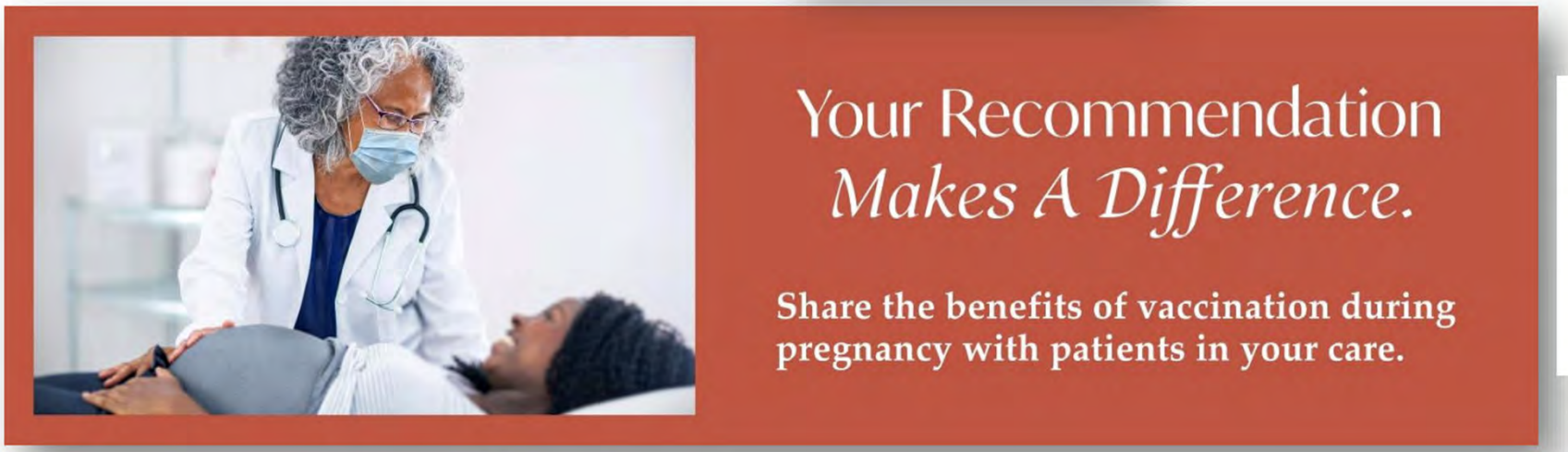


Figure represents recommended timing of immunization product deployment for most of the continental U.S. In jurisdictions with seasonality that differs from most of the continental United States (e.g., Alaska, jurisdictions with tropical climates), providers should follow state, local, or territorial guidance on timing of administration

CDC Campaign: From Me, To You

Implementation



RSV Adult vaccines

Limitations of RSV vaccine trials

	Randomized RSV vaccine trials[1,2]	Observational RSV VE studies
Immunocompromised patients	Excluded	Included
Adults aged ≥80 years	<8% of participants	≥25% of included adults
Any chronic condition	<52% of participants	≥94% of included adults
Endpoint or outcome	Symptomatic, RSV-associated ***lower respiratory tract disease***	RSV-associated ***emergency department (ED) visits***, ***hospitalization***, ***critical illness[3]***

[1]Papi A, et al; AReSVi-006 Study Group. Respiratory syncytial virus prefusion F protein vaccine in older adults. *N Engl J Med*. 2023;388(7):595-608
[2]Walsh EE, et al; RENOIR Clinical Trial Group. Efficacy and safety of a bivalent RSV prefusion F vaccine in older adults. *N Engl J Med*. 2023;388(16):1465-1477
[3]Critical illness is defined as intensive care unit admissions or death

Effectiveness

Observational VE studies show RSV vaccines protect against severe RSV disease, similar to results from trials, although endpoints differ

Outcome	Analysis	Vaccine efficacy/effectiveness, % (95% CI)
Symptomatic, RSV-associated lower respiratory tract disease (LRTD)	GSK trial (≥2 or 3 sx LRTD, primary endpoint)†	83 (58–94)
	Pfizer trial (≥2 sx LRTI, co-primary endpoint)*	67 (29–86)
	Pfizer trial (≥3 sx LRTI, co-primary endpoint)*	86 (32–99)
RSV-associated hospitalization	IVY Network, adults ≥60 years§	75 (50–87)
	VISION, adults ≥60 years, immunocompetent	80 (71–85)
	VHA, adults ≥60 years§	82 (69–89)
	Medicare ESRD, otherwise immunocompetent, ≥65y	72 (41-87)
	VISION, immunocompromised	73 (48–85)
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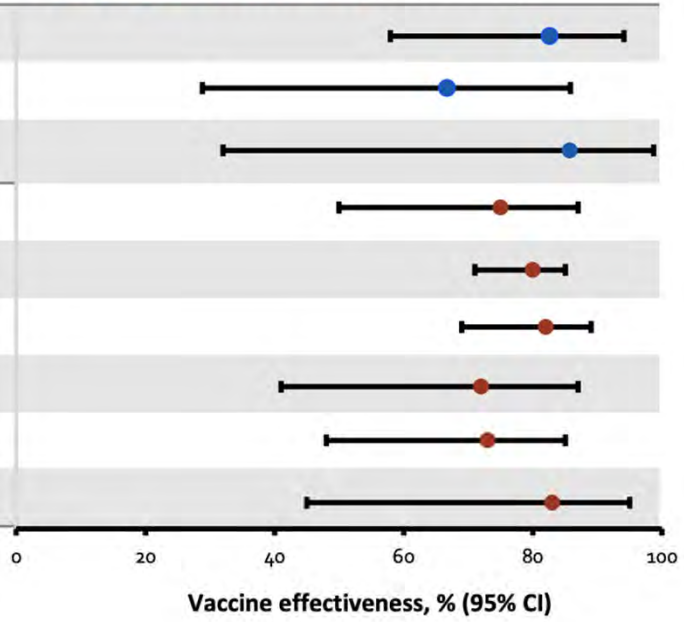

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§ Includes patients with immunocompromising conditions in the displayed VE estimate.

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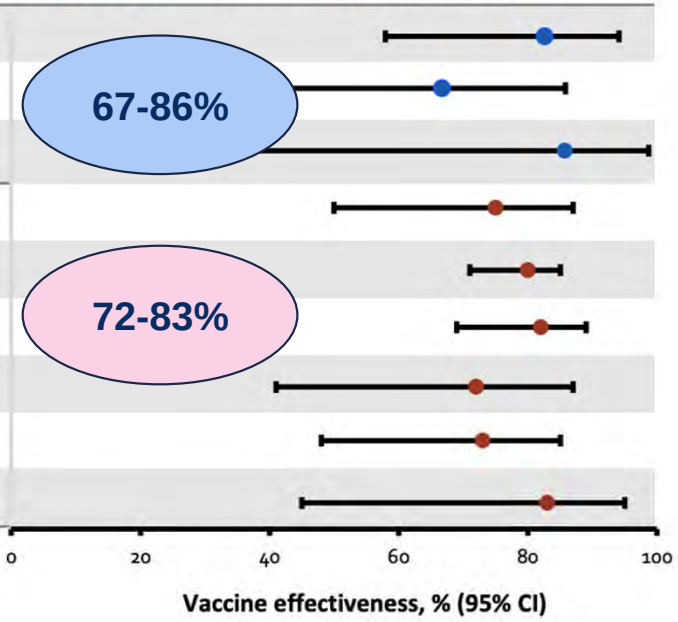

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Conclusions

- Under real-world conditions, RSV vaccination (GSK or Pfizer) provided protection against severe RSV disease among US adults aged ≥60 years in this first season of use

- These results build on those from RSV vaccine trials in two ways:
  - Provide evidence of VE against RSV-associated ED visits, hospitalizations, and critical illness
  - Demonstrate protection in a population that more closely represents those at high-risk of severe RSV disease, including
    - Adults aged 75 years or older
    - Adults with a composite of various immunocompromising conditions
    - Adults with underlying conditions, especially cardiopulmonary disease

- Ongoing monitoring of RSV VE is needed to confirm findings from this season and assess durability of RSV vaccine protection

Safety: Is the RSV vaccine associated with Guillain-Barré Syndrome?

- Post-licensure safety studies
  - Observed versus expected
  - Self-controlled case series analysis
- Very rare event
- Results mixed, highly uncertain
- Chart reviews ongoing
- Benefits currently outweigh theoretical and unproven risk
- Ongoing question influenced discussion around change in ACIP recommendation

Implementation: Transition Away from SDM

- CDC recommends a single dose of RSV vaccines for:
  - All adults ages 75 and older
  - Adults ages 60-74 who are at increased risk of severe RSV disease
- Define "Increased Risk"
  - Cardiovascular disease, lung disease, ESRD
  - Diabetes with end organ damage
  - Severe Obesity (body mass index ≥40 kg/m$^{2)}$
- And more!

Implementation Best Practices

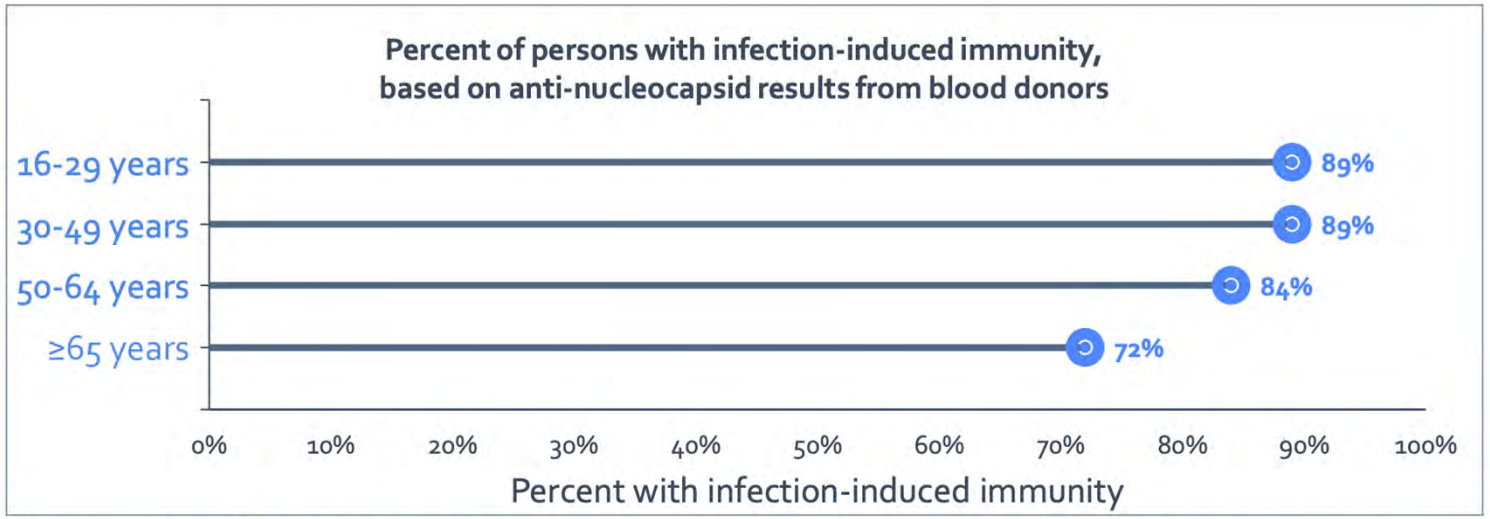
- Benefit to give in late summer/early fall
  - Not a formal recommendation, can be given year round
- Single lifetime dose; benefits of revaccination unclear
- Co-administration is safe and acceptable

COVID-19

Effectiveness: Aren't we all immune anyway?

Context for interpreting COVID-19 VE across age groups

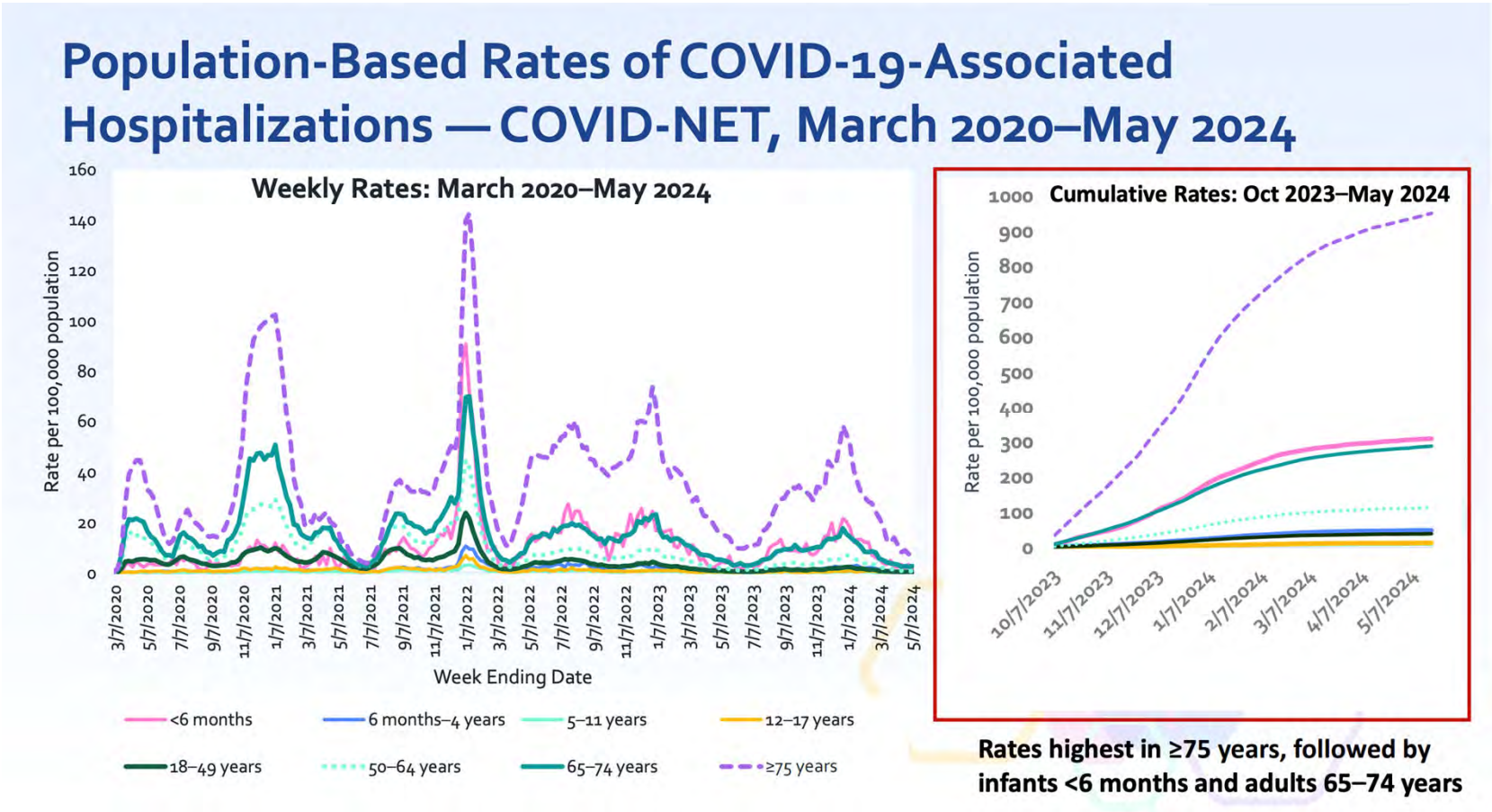
- High rates of SARS-CoV-2 infection-induced immunity by July – August 2023.*



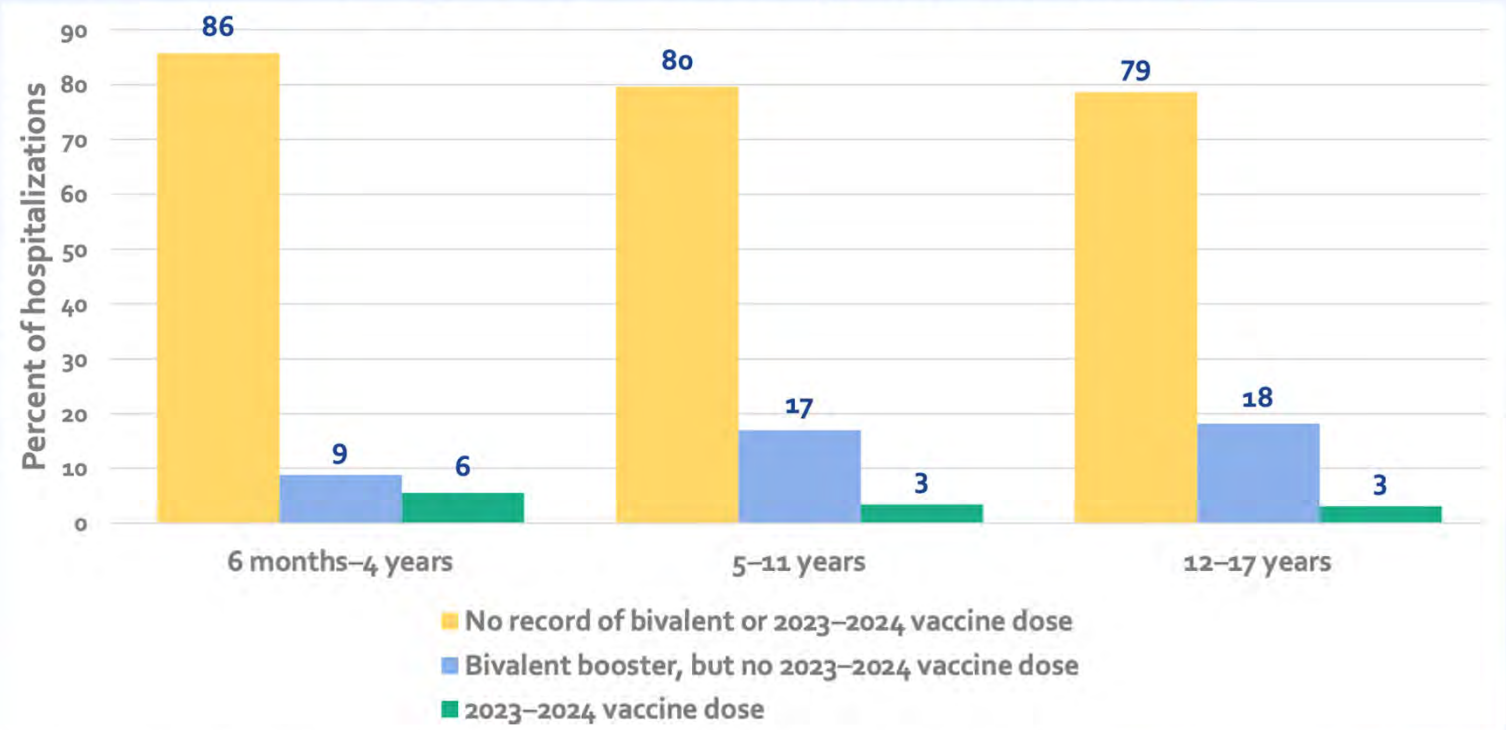
VE findings should be interpreted as the incremental benefit provided by COVID-19 vaccination in a population with a high prevalence of vaccine- and infection-induced immunity.

* Internal CDC data. Data on persons aged ≥16 years is from a longitudinal, national cohort of >35,000 blood donors.
Methods and prior data available at: https://covid.cdc.gov/covid-data-tracker/#nationwide-blood-donor-seroprevalence-2022

Who is getting hospitalized from COVID-19?



Vaccination Status among Children and Adolescents Ages ≤17 Years with COVID-19-associated Hospitalizations, by Age Group — COVID-NET, October 2023–March 2024



- **5%** of children and adolescents ages ≤17 years with COVID-19-associated hospitalizations **received a 2023–2024 vaccine dose.**

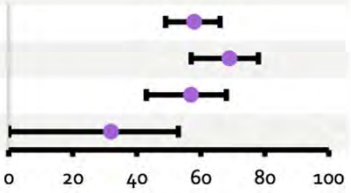
***No record of bivalent or 2023–2024 vaccine dose**: No recorded doses of COVID-19 bivalent or the 2023-2024 vaccine dose since August 2022. **Bivalent booster, but no 2023–2024 vaccine dose**: Received COVID-19 bivalent booster vaccination but no record of receiving 2023-2024 vaccine dose since August 2022. **2023–2024 vaccine dose:** Received 2023-2024 vaccine dose. Persons with unknown vaccination status are excluded. Hospitalizations are limited to those with COVID-19 as the presenting complaint upon admission.*

Effectiveness

VISION: VE of *2023-2024 COVID-19 vaccine* against *critical illness* among immunocompetent adults aged ≥18 years, by age group

September 2023 – May 2024

Age group/2023-2024 COVID-19 vaccination status/days since dose	Total encounters	SARS-CoV-2-test-positive N (%)	Median interval since last dose among those vaccinated, days (IQR)	Adjusted VE (95% CI)
≥18 years				
No 2023-2024 COVID-19 dose (ref)	58,576	1,152 (2)	694 (452-855)	**Ref**
2023-2024 COVID-19 dose, ≥7 days	12,402	119 (1)	85 (46-128)	**58 (49-66)**
2023-2024 COVID-19 dose, 7-59 days earlier	4,151	38 (1)	34 (21-47)	**69 (57-78)**
2023-2024 COVID-19 dose, 60-119 days earlier	4,616	50 (1)	88 (74-104)	**57 (43-68)**
2023-2024 COVID-19 dose, 120-179 days earlier	3,635	31 (1)	147 (133-162)	**32 (0-53)***



CDC unpublished data. Critical illness defined as admission to an intensive care unit (ICU) or death while hospitalized or ≤28 days after hospital admission. VE was calculated as (1 – odds ratio) x 100%, estimated using a test-negative case-control design, adjusted for age, sex, race and ethnicity, geographic region, and calendar time.

*Some estimates are imprecise, which might be due to a relatively small number of persons in each level of vaccination or case status. This imprecision indicates that the actual VE could be substantially different from the point estimate shown, and estimates should therefore be interpreted with caution. Additional data accrual could increase precision and allow more precise interpretation.

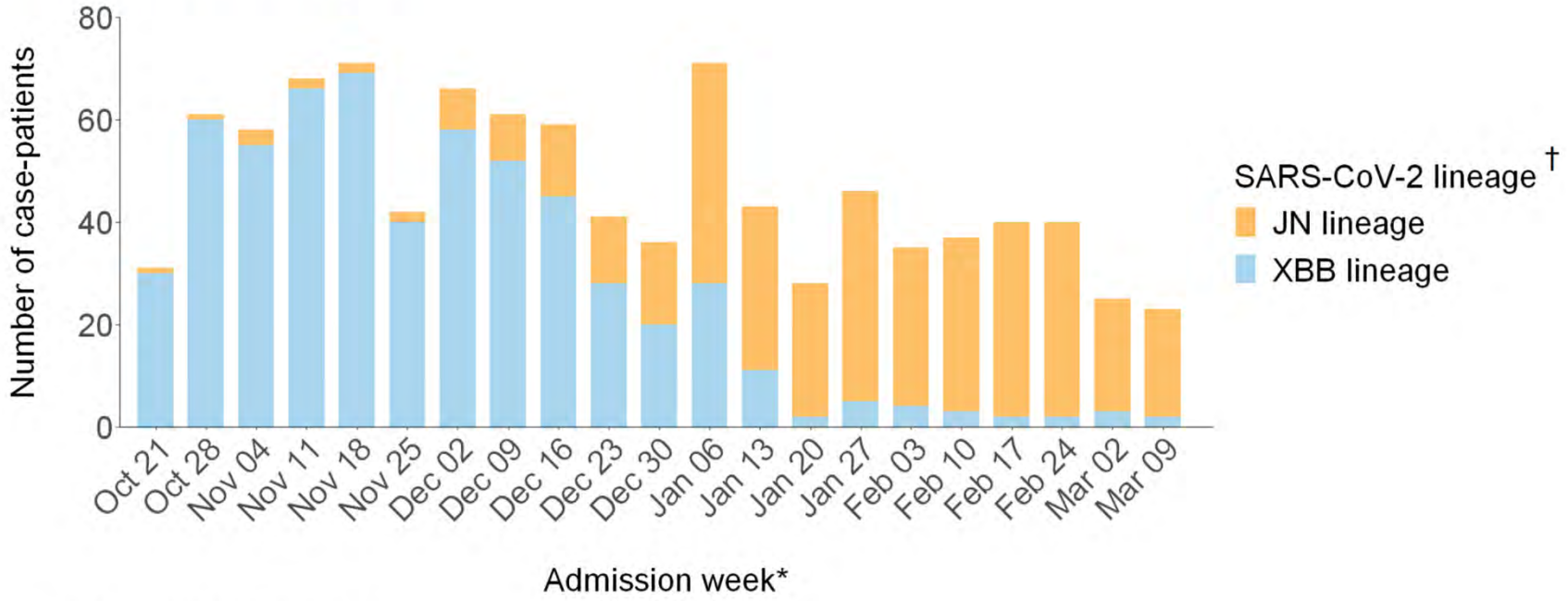
Effectiveness

- Effectiveness duration critical as COVID-19 does not have seasonality
- Impacts recommendation on how often to vaccinate high-risk individuals
- Hospitalization occurring in high-risk groups
  - Unvaccinated infants
  - Elderly, immunocompromised, complex medical conditions, pregnancy

The case for updating again

IVY: Number of COVID-19 case-patients by hospital admission week and SARS-CoV-2 lineage

October 18, 2023 – March 9, 2024



* Dates are for the end of the admission week.

† JN lineages comprised BA.2.86 and its descendants. XBB lineages comprised all other co-circulating lineages.

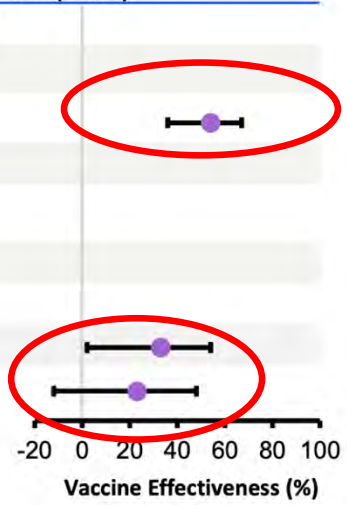
Identification of a SARS-CoV-2 lineage through viral whole-genome sequencing was successful for 63% of case-patients during the analysis period.

The case for updating again

IVY: VE of *2023–2024 COVID-19 vaccine* against *hospitalization* among adults aged ≥18 years*, by SARS-CoV-2 lineage and time since dose

October 18, 2023 – March 9, 2024

COVID-19 dosage pattern	COVID-19 control-patients		COVID-19 case-patients		VE** (95% CI)
	N (Col %)	Median interval since last dose among vaccinated, days (IQR)	N (Col %)	Median interval since last dose among vaccinated, days (IQR)	
XBB lineages†					
No 2023-2024 COVID-19 dose (ref)	3736 (82)	688 (429–834)	532 (91)	557 (385–751)	Ref
2023-2024 COVID-19 dose, 7–89 days earlier	568 (12)	47 (26–68)	47 (8)	44 (22–67)	**54 (36–67)**
2023-2024 COVID-19 dose, 90–179 days earlier	276 (6)	118 (106–131)	6 (1)	92 (91–105)	§
JN lineages†					
No 2023-2024 COVID-19 dose (ref)	3736 (82)	688 (429–834)	319 (80)	746 (479–855)	Ref
2023-2024 COVID-19 dose, 7–89 days earlier	568 (12)	47 (26–68)	38 (10)	56 (31–74)	**33 (2–54)**¶
2023-2024 COVID-19 dose, 90–179 days earlier	276 (6)	118 (106–131)	40 (10)	118 (107–130)	**23 (-12 to 48)**¶



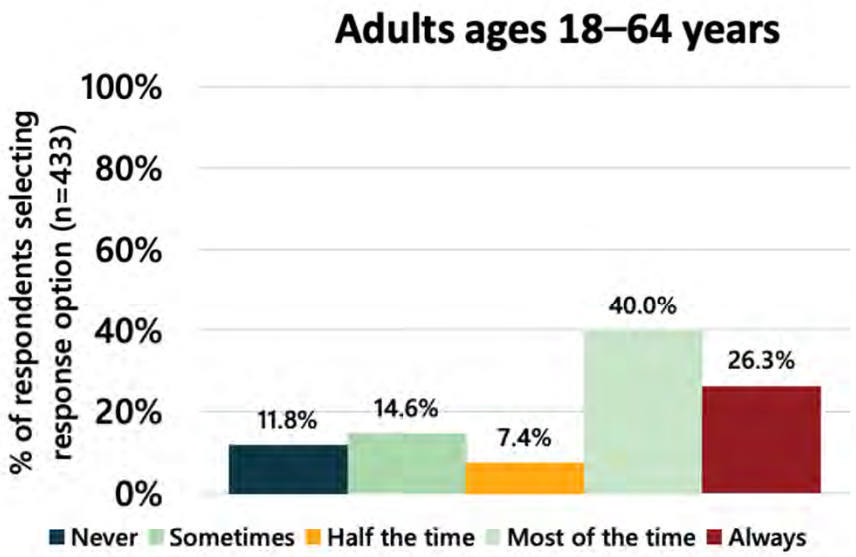
* These results include both immunocompetent and immunocompromised persons.
† JN lineages comprised BA.2.86 and its descendants. XBB lineages comprised all other co-circulating lineages.
§ Based on timing of recommendations to receive 2023–2024 COVID-19 vaccines and JN lineage emergence, limited numbers of individuals with XBB infection were 90–179 days from their updated dose, precluding estimation of VE within this stratum.
¶ Some estimates are imprecise, which might be due to a relatively small number of persons in each level of vaccination or case status. This imprecision indicates that the actual VE could be substantially different from the point estimate shown, and estimates should therefore be interpreted with caution.
** VE estimates adjusted for age, sex, race and ethnicity, geographic region, calendar time, and Charlson comorbidity index.

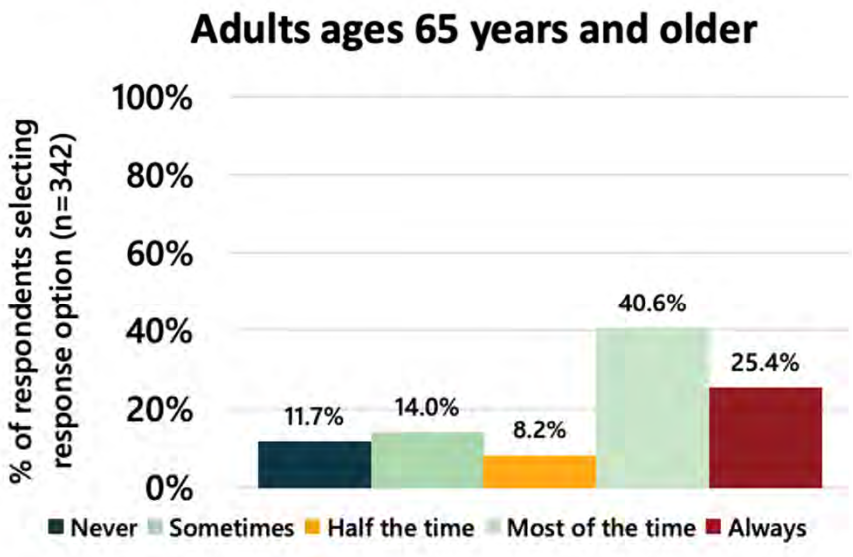
CDC unpublished data.

Implementation

Frequency of recommending COVID-19 vaccination to eligible adult patients

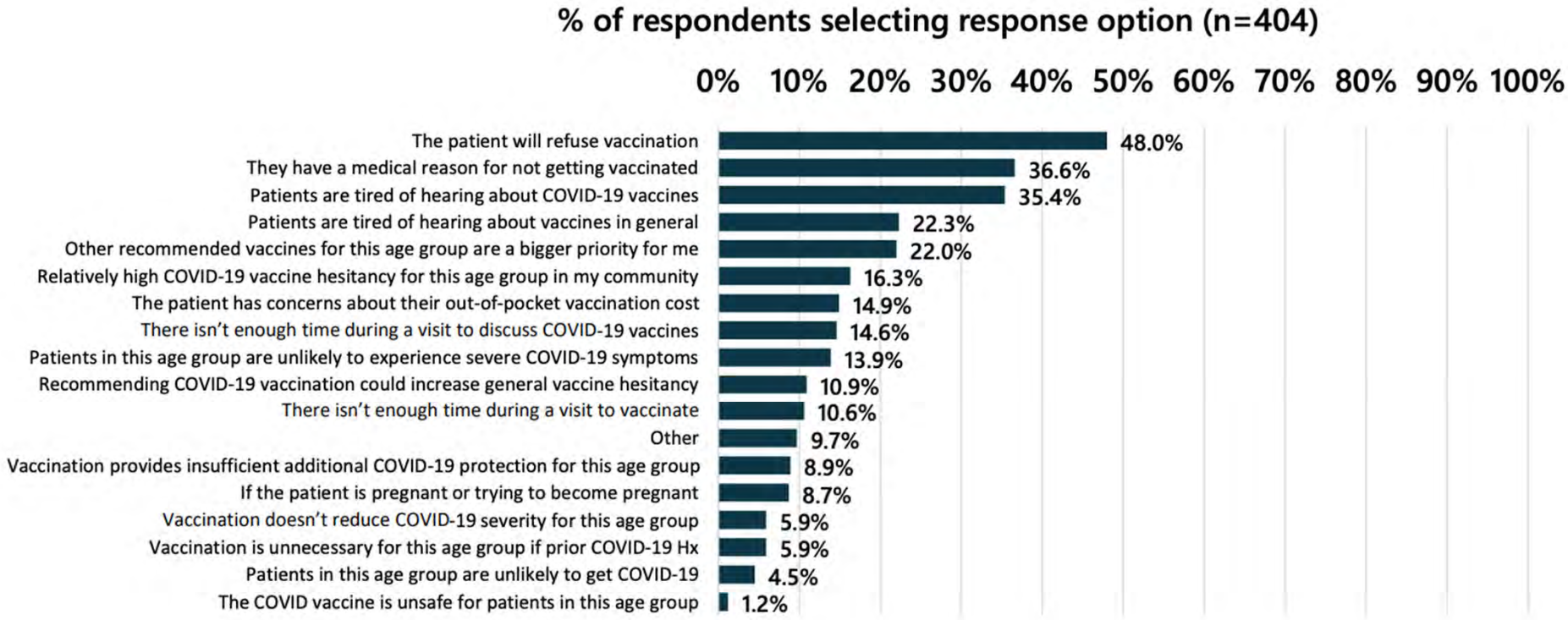
Most providers reported recommending the COVID-19 vaccine to adults most of the time or always.





Data source: HaPPI Survey Collaborative, University of Iowa; RAND Corporation; CDC

Reasons reported for NOT recommending COVID-19 vaccine to eligible adult patients (18–64 years)

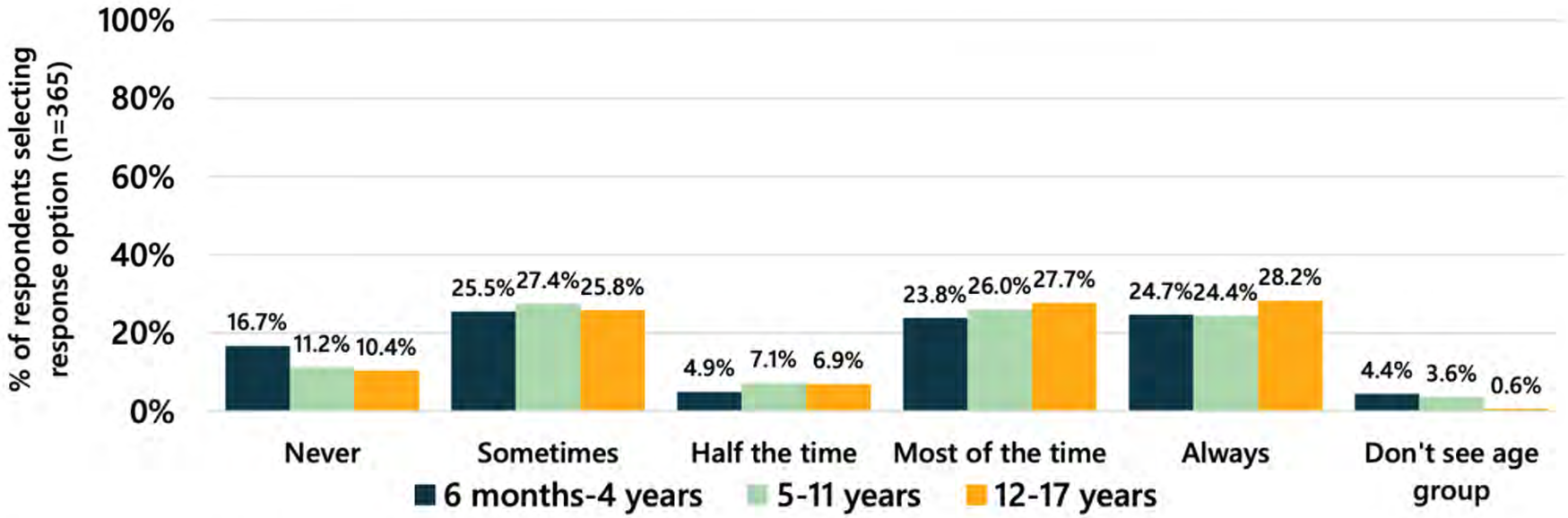


Data source: HaPPI Survey Collaborative, University of Iowa; RAND Corporation; CDC

Implementation

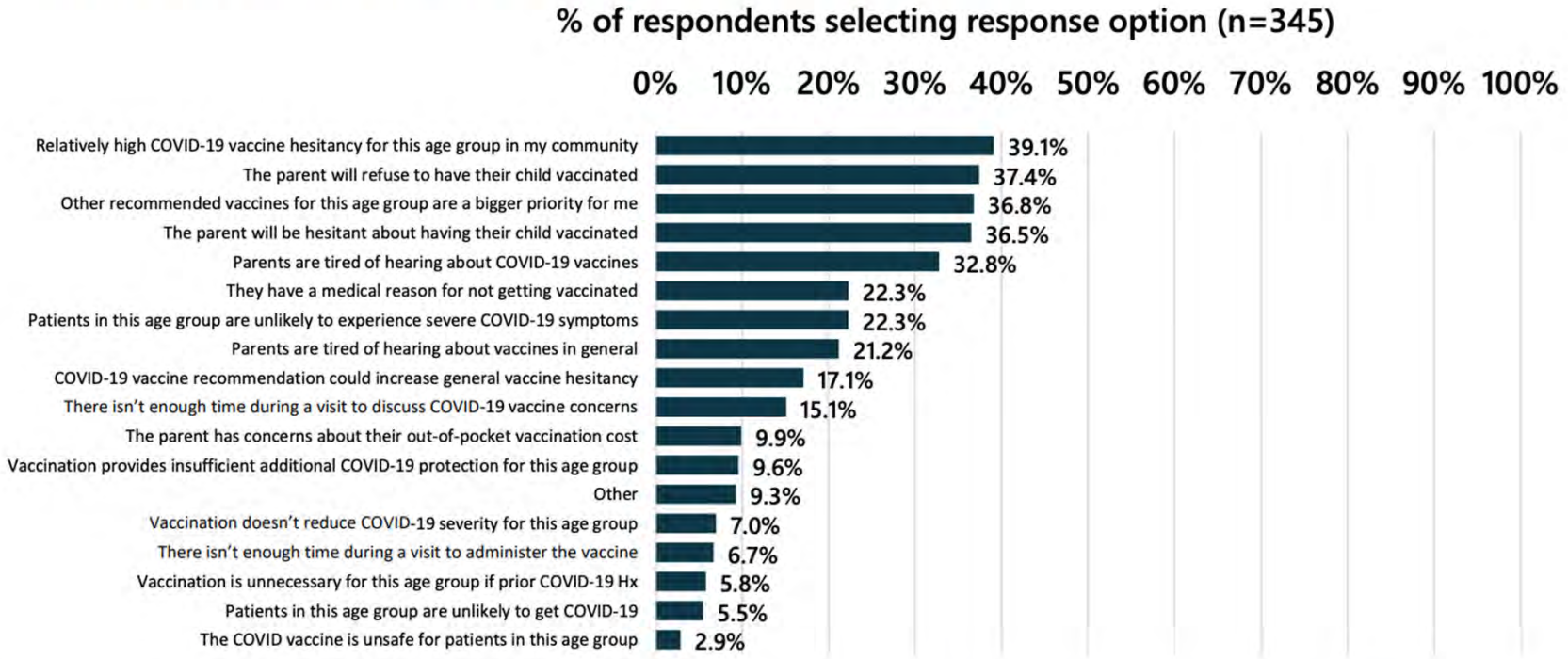
Frequency of recommending on-site COVID-19 vaccination to eligible pediatric patients

Approximately the same proportion of providers reported recommending the vaccine sometimes, most of the time, and always.



Data source: HaPPI Survey Collaborative, University of Iowa; RAND Corporation; CDC

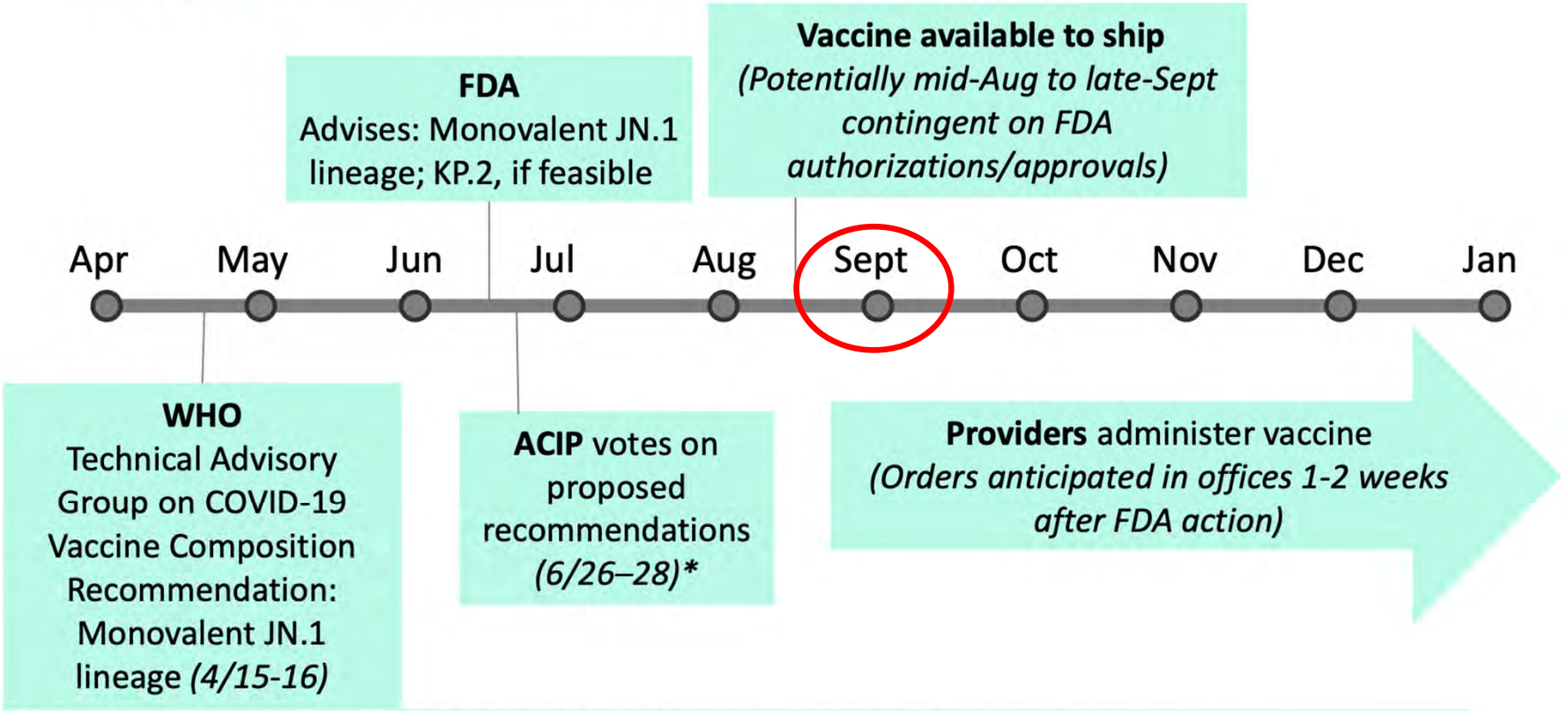
Reasons reported for NOT recommending COVID-19 vaccine to eligible pediatric patients



Data source: HaPPI Survey Collaborative, University of Iowa; RAND Corporation; CDC

Implementation

Prospective 2024 COVID-19 vaccine timeline



***CDC publishes** MMWR policy note following ACIP and FDA action (potentially late August to late September).
****CDC** updates COVID-19 Vaccine Interim Clinical Considerations immediately following FDA action.

Influenza 2024-2025

Influenza General Recommendations

- All influenza vaccines will be trivalent
- No influenza B/Yamagata component
  - Not detected since March 2020
- Update to the influenza A(H3N2) component:
  - An A/Victoria/4897/2022 (H1N1)pdm09-like virus for egg-based vaccines or an A/Wisconsin/67/2022 (H1N1)pdm09-like virus for cell and recombinant vaccines
  - An A/Thailand/8/2022 (H3N2)-like virus for egg-based vaccines or an A/Massachusetts/18/2022 (H3N2)-like virus for cell and recombinant vaccines
  - A B/Austria/1359417/2021 (B/Victoria lineage)-like virus

Solid organ transplant

- Routine annual influenza vaccination is recommended for all persons aged ≥6 months without contraindications.
- All persons should receive an age-appropriate influenza vaccine (i.e., one approved for their age), with the following exception: **solid organ transplant recipients aged 18 through 64 years on immunosuppressive medication regimens may receive either HD-IIV3 or aIIV3 as an acceptable option (without a preference over other age-appropriate IIV3s or RIV3).**

Influenza A (H5N1) Update

- H5N1 infections confirmed in dairy cattle herds on over 190 farms in 13 states
- All patients have recovered
- No human-to-human transmission
- Overall risk remains LOW
- **Vaccine available, but <u>No current vaccine recommendation</u>**

Targeted H5 surveillance (since March 24, 2024)

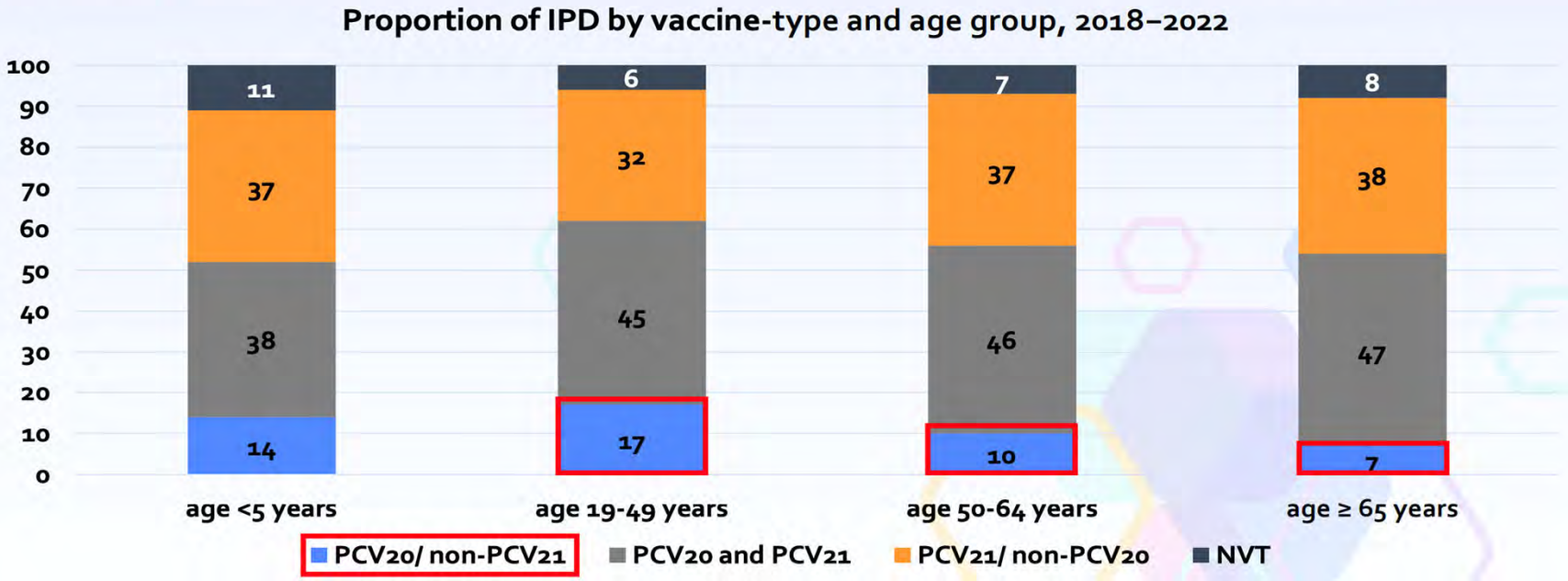
Total people monitored	Total people tested	Human cases
4,500+ after exposure to infected animals	**230+** after exposure to infected animals	**13** total reported human cases in the United States

https://www.cdc.gov/bird-flu/situation-summary/index.html

Pneumococcal vaccines: PCV 21

Epidemiology

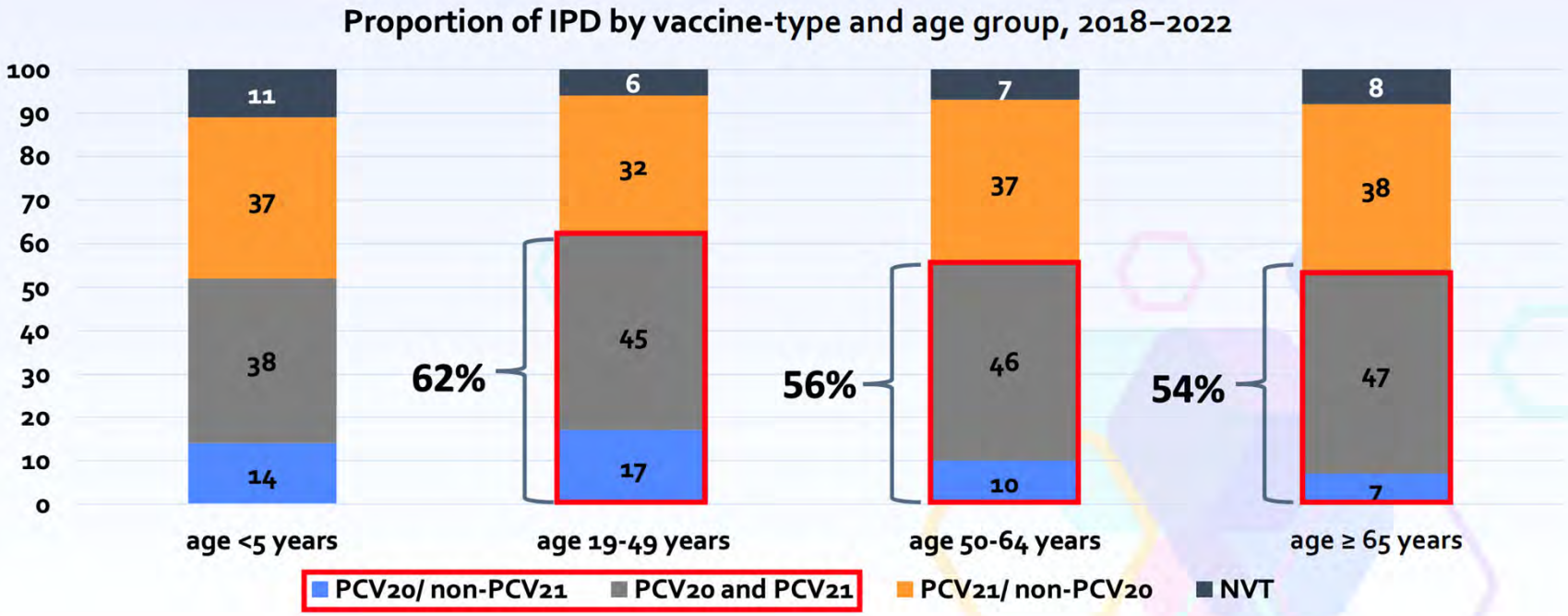
The proportion of IPD cases due to PCV20/non-PCV21 serotypes is relatively lower in older vs younger adults



CDCsActive Bacterial Core surveillance

Epidemiology

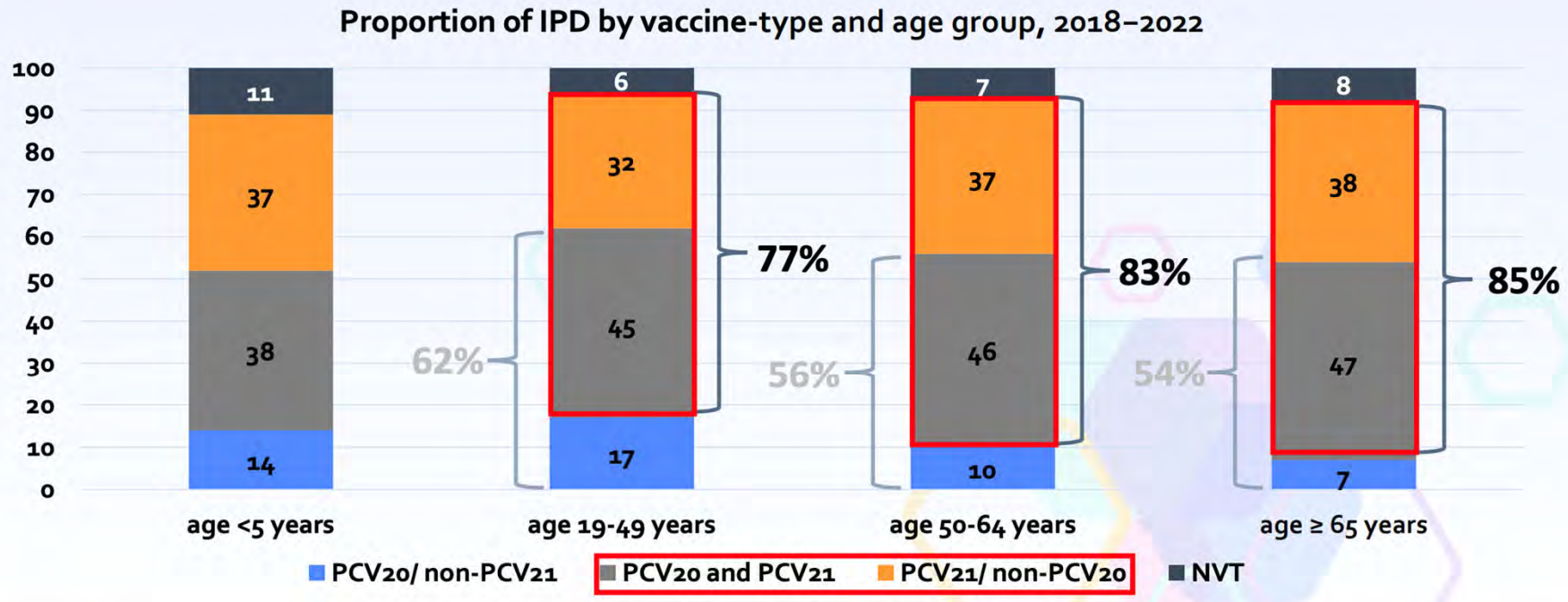
54–62 % of IPD cases in adults were due to PCV20 serotypes



CDCsActive Bacterial Core surveillance

Epidemiology

77–85% of IPD cases in adults were due to PCV21 serotypes



Implementation

PCV-naïve adults (or adults with unknown history)

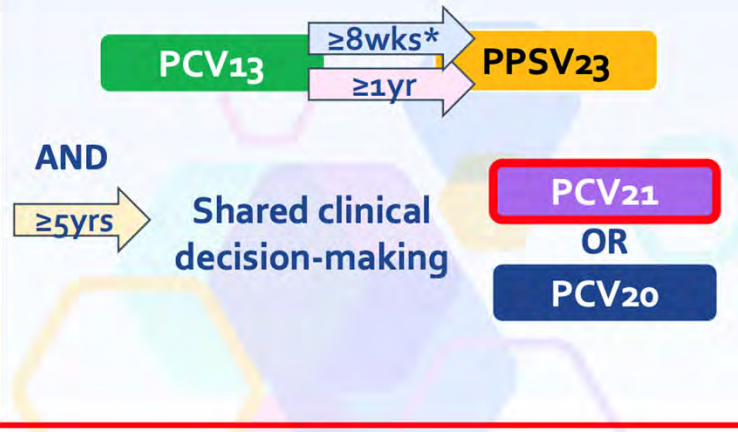
Underlying conditions	Previous vaccination history	Age 19–64 years	Age ≥65 years
None	None	No vaccine recommendation	PCV21 OR PCV20 OR PCV15 → ≥1yr → PPSV23*
Chronic medical conditions	None	PCV21 OR PCV20 OR PCV15 → ≥8wks† / ≥1yr → PPSV23*	
CSF leak, cochlear implant	None		
Immuno-compromised	None		

*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

Pneumococcal Vaccine for Adults Aged ≥19 Years: Recommendations of the Advisory Committee on Immunization Practices, United States, 2023 | MMWR (cdc.gov)

Implementation

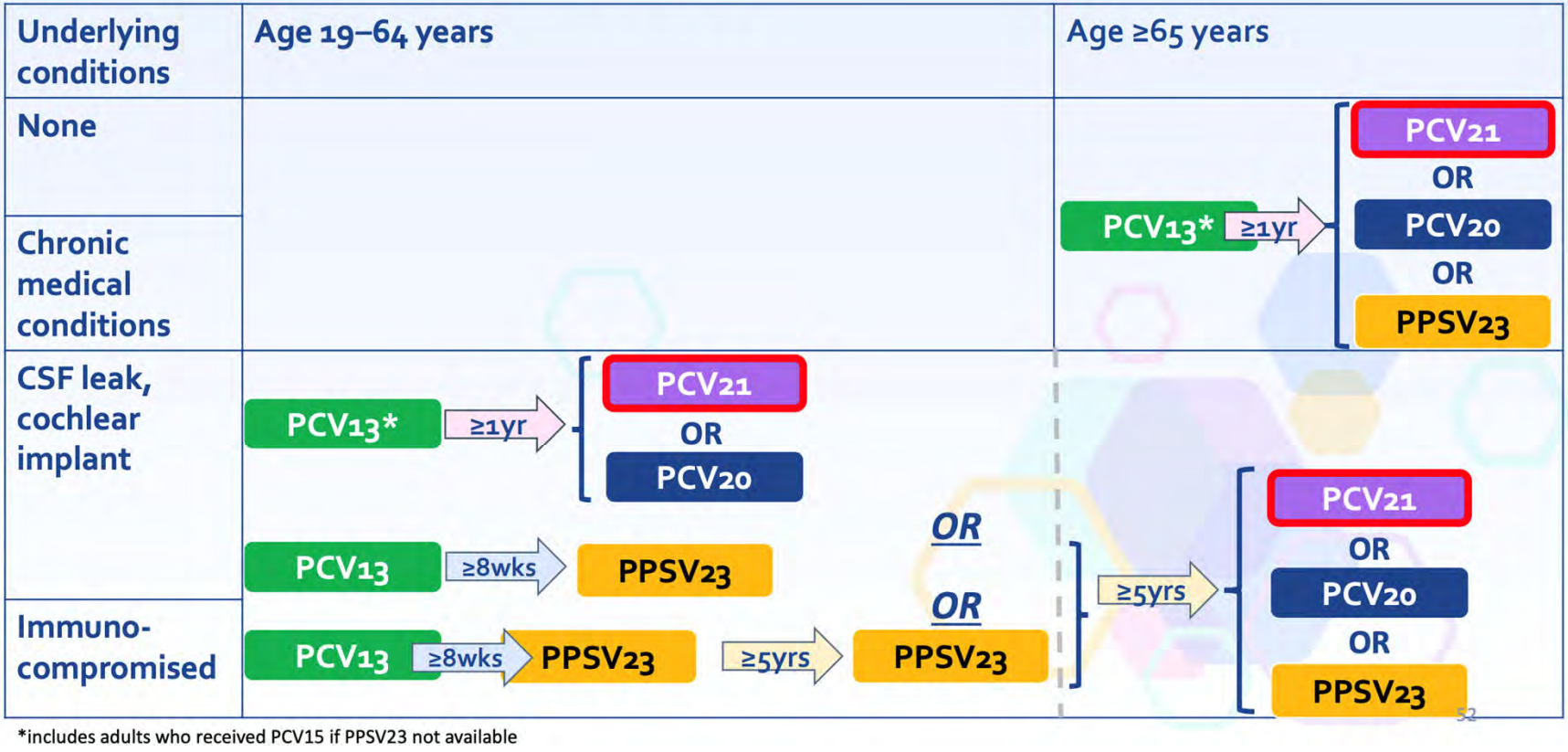
PCV-experienced adults who completed the recommended vaccine series

Underlying conditions	Age 19–64 years	Age ≥65 years
None	No vaccine recommendation	
Chronic medical conditions		
CSF leak, cochlear implant		
Immuno-compromised		

Pneumococcal Vaccine for Adults Aged ≥19 Years: Recommendations of the Advisory Committee on Immunization Practices, United States, 2023 | MMWR (cdc.gov)

Implementation

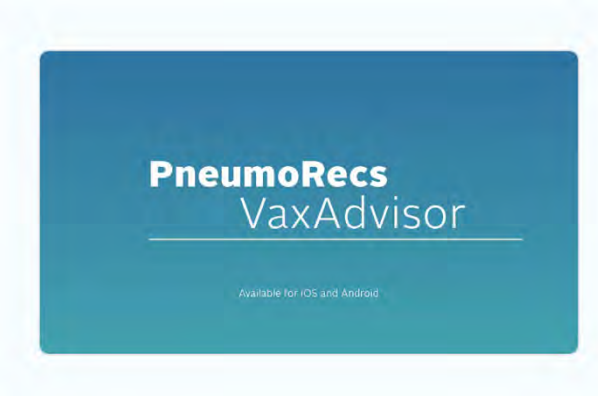
PCV-experienced adults who have not completed the recommended vaccine series



*includes adults who received PCV15 if PPSV23 not available

Ongoing Work

- Following serotype 4 disease
- Determining if lower age should be 50 instead of 65
- Determining benefit to coverage for people down to age 19
- Implementation challenges of multiple pneumococcal products which could have different recommendations
- Continue to use app for complicated histories



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