

Maternal Immunization Updates for the 2024-2025 Respiratory Virus Season

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Disclosure

I, Ai-ris Y. Collier, have been asked to disclose any relevant financial relationships with ACCME-defined commercial entities that are either providing financial support for this program or whose products or services are mentioned during this presentation.

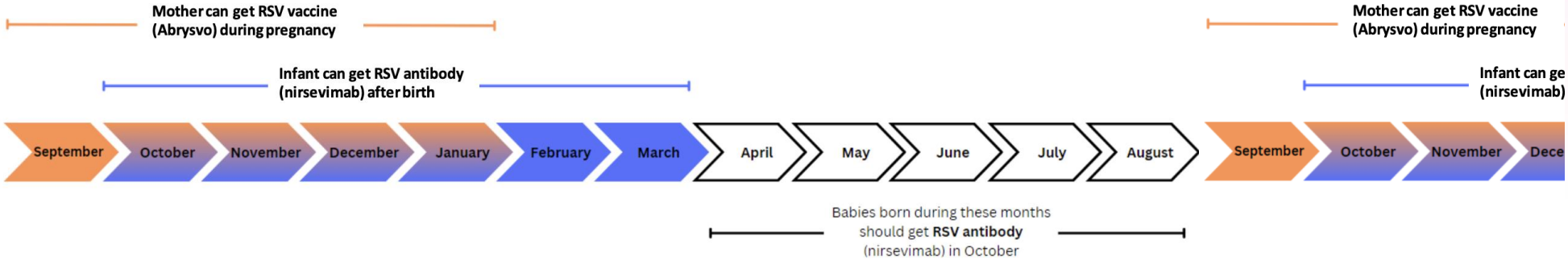
I have collaborations/contracts with GSK, Pfizer, Sanofi, and Hookipa Biotech, and Imunon to conduct clinical trials related to vaccines and long COVID

I have contracts with Mirvie, Pfizer, Laborie for clinical trials in pregnancy

My spouse is a paid employee at Medtronic

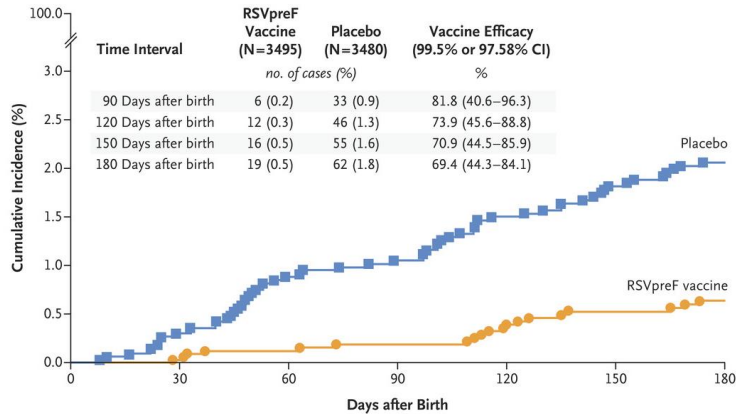
I do not serve on advisory boards, have equity, stock, receive royalties, or other income from these entities

We implemented two infant RSV prevention strategies rapidly in the 2023-2024 season!



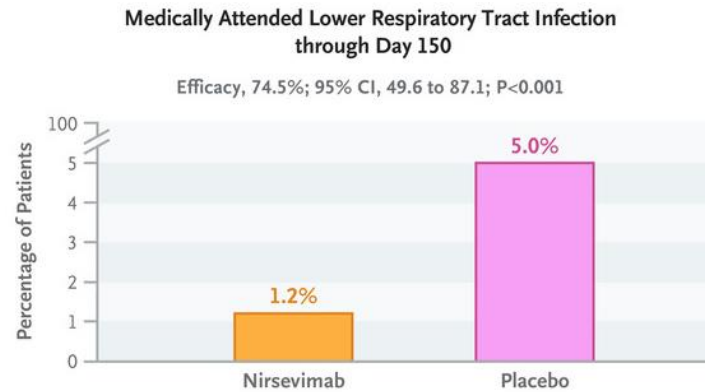
RSVpreF maternal vaccine Medically-attended *Severe* RSV-associated lower resp tract infection

Vaccine efficacy: 82% [CI: 41-96%] at 3 mo
Vaccine efficacy: 69% [CI: 44-84%] at 6 mo



Nirsevimab infant immunization Medically-attended RSV-associated lower resp tract infection

Vaccine efficacy: 80% [CI: 66-88%] at 5 mo



**RSV is the
LEADING CAUSE
of infant
hospitalization
in the U.S.**



www.cdc.gov/rsv

Kampmann et al. N Engl J Med. 2023. PMID: 37018474

Hammitt et al. N Engl J Med. 2022. PMID: 35235726

Simões et al. Lancet Child Adolesc Health. 2023. PMID: 36634694

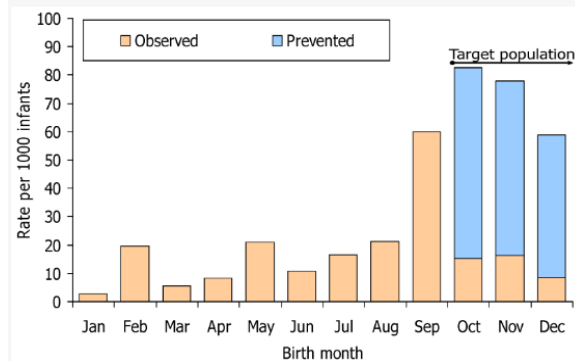
RSV prevention was highly effective, particularly in regions of high use (Spain and Italy)

First season nirsevimab product effectiveness (PE) against medically attended RSV-associated ARI and RSV-associated hospitalization – NVSN, October 2023 – March 2024*

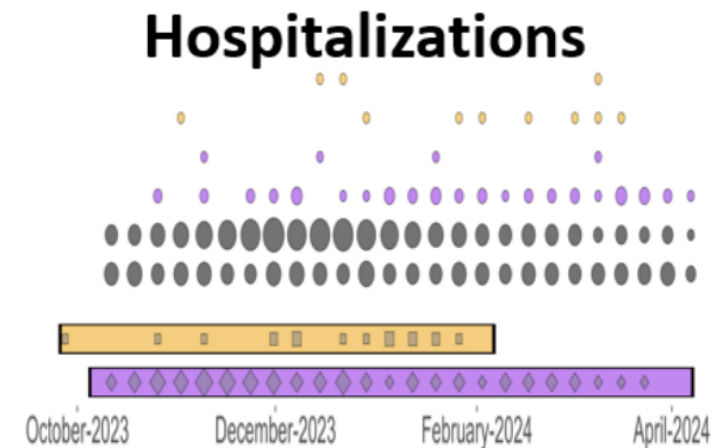
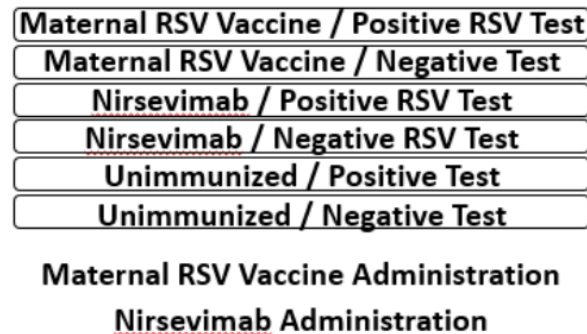
Outcome Nirsevimab dosage pattern	Total encounters	RSV-positive encounters N (Row %)	Median days since dose (IQR)	Adjusted PE (95% CI)†
Medically Attended RSV-associated ARI episode‡				
No nirsevimab doses	1,575	755 (48)	N/A	ref
Nirsevimab, ≥7 days prior§	120	9 (8)	42 (21-73)	89 (77-94)
RSV-associated hospitalization				
No nirsevimab doses	807	526 (65)	N/A	ref
Nirsevimab, ≥7 days prior	63	6 (10)	38 (15-67)	91 (79-96)

Nirsevimab was effective against medically attended RSV-associated ARI episodes and RSV-associated hospitalization.

Figure 4. Observed incidence of hospitalisation for confirmed respiratory syncytial virus infection and estimated incidence of hospitalisations prevented by birth month among children born in Navarre in 2023 and follow-up from October 2023 to 14 January 2024.



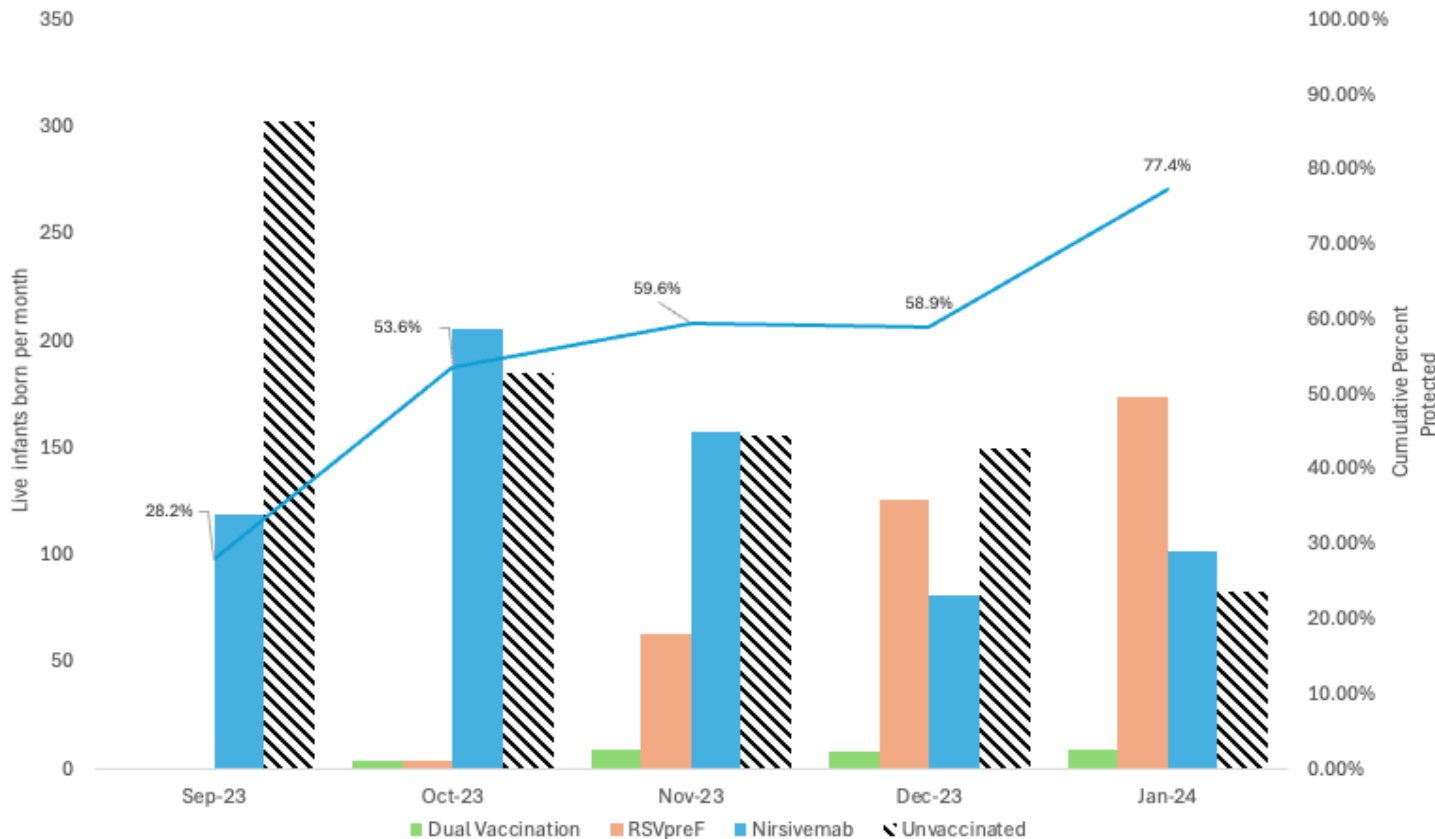
- Nirsevimab appears highly effective in short follow-up period
- Unable to estimate maternal RSV vaccine effectiveness during the 2023-24 season
 - Limited uptake of maternal RSV vaccine
 - Early onset of the 2023-2024 RSV season
 - Timing of vaccine rollout



Ezpeleta et al. *Vaccines* 2024, 12(4)

<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2024-06-26-28/05-RSV-Mat-Peds-Jones-508.pdf>

Implementation of RSV prevention at BIDMC was dynamic; improved by administration at prenatal care clinics and birth hospitalization



Findings at BIDMC:

- Uncertain insurance coverage → slow start to RSVpreF
- Nirsevimab supply shortage → overcome by later RSVpreF uptake
- Disparities in maternal RSVpreF administration
- Equitable nirsevimab administration

Ways to improve this year:

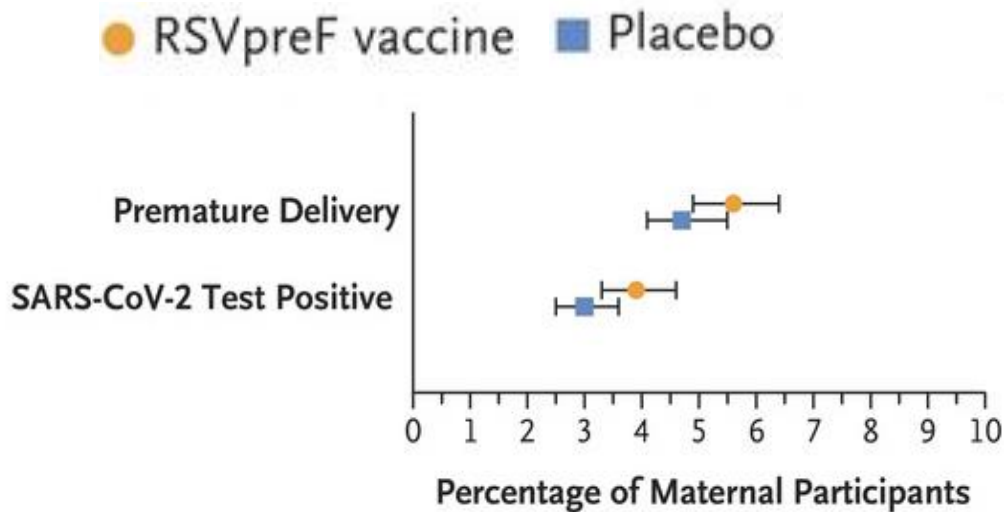
- RSVpreF vaccines in prenatal clinics
- Infant nirsevimab at birth hospitalization

Adverse events after RSVpreF maternal vaccine

Preterm birth imbalance

Not statistically significant

60% occurred >30d from vaccination; Unlikely biologic reason for PTB to be related to vaccine



	RSVpreF	Placebo
Trial participants 24-36w N= 7126	5.7% (4.9-6.5%)	4.7% (4.1-5.5%)
Trial participants 32-36w N= 3232	4.2% (3.3-5.3%)	3.7 (2.8-4.7%)
US participants 32-36w N= 1453	4.0%	4.4%

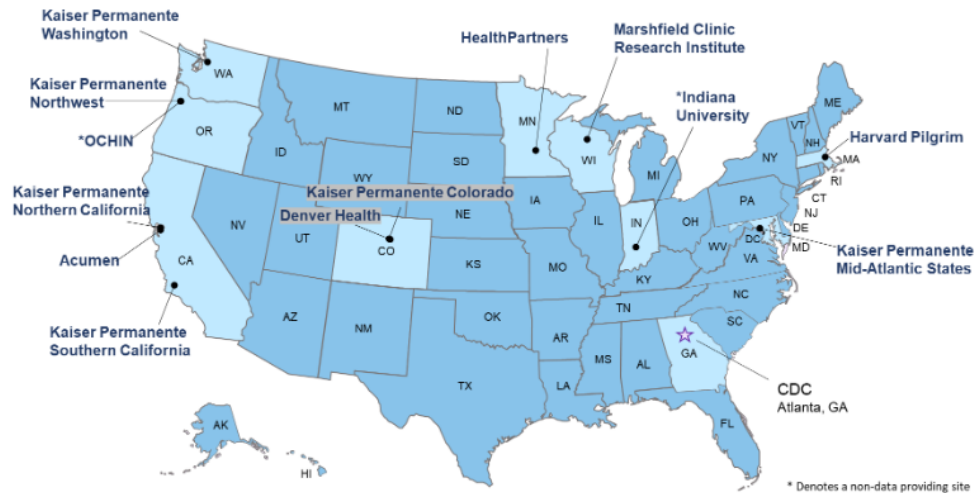
Data presented as % preterm birth <37w (95% confidence interval)

Post-market surveillance is ongoing and important

- Just like COVID-19 vaccine surveillance
 - CDC V-safe patient reporting
 - CDC Vaccine Adverse Event Reporting System (VAERS)
 - CDC Vaccine Safety Datalink (VSD)

Participating VSD Healthcare Organizations

Sites that do not provide data are denoted with an asterisk(*).



Welcome to V-safe!

V-safe is a web-based tool that checks in on you after your vaccinations.

V-safe is currently available for people who have received:

- RSV vaccine

<https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/reportingaes.html>
<https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/v-safe/index.html>
<https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html#evaluate>

There are 2 ways to submit a report to the Vaccine Adverse Event Reporting System (VAERS)

Reporting adverse events to VAERS helps scientist at CDC and FDA keep vaccines safe.

Option 1: [Submit a VAERS Report online](#) (Preferred)

The online VAERS Report must be completed and submitted in the same session; it cannot be saved and edited at a later time. Note: sessions time out after 20 minutes of inactivity; no information is saved.

Option 2: [Download a Writable PDF Form and upload when ready](#)

The Writable PDF Form can be downloaded and completed electronically on your own time. When ready, return to the VAERS Writable PDF web page (use link above) and follow **Step 2** instructions to upload the form.

More information on [reporting an adverse event to VAERS](#). If you need further assistance, please email info@VAERS.org or call 1-800-822-7967.



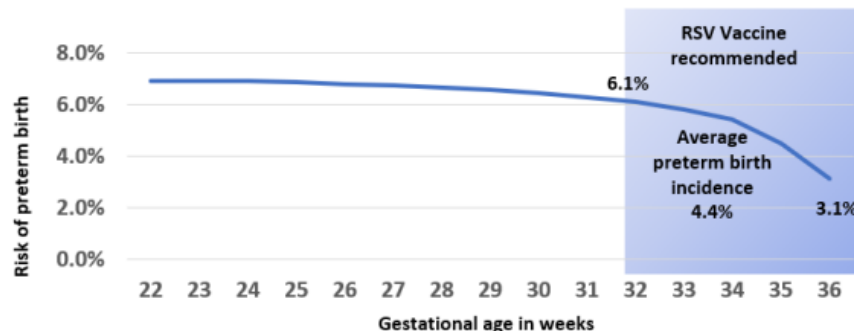
Post-market data on RSVpreF suggests safe and low rates of adverse pregnancy outcome

Table 2. Pregnancy Outcomes Between Patients Who Had RSV Vaccination During Pregnancy Documented in Their Electronic Health Record vs Those Who Did Not

Pregnancy outcome	Patients, No. (%)		OR (95% CI)	aOR (95% CI) ^a	HR (95% CI) ^b
	RSV vaccine (n = 1011)	No RSV vaccine (n = 1962)			
Primary outcome					
Preterm birth <37 weeks' gestation	60 (5.9)	131 (6.7)	0.88 (0.64-1.20)	0.87 (0.62-1.20)	0.93 (0.64-1.34)
Secondary outcomes					
Hypertensive disorders of pregnancy	203 (20.1)	355 (18.1)	1.14 (0.94-1.38)	1.10 (0.90-1.35)	1.43 (1.16-1.77)
Gestational hypertension ^c	153 (15.1)	273 (13.9)	NA	NA	NA
Preeclampsia	67 (6.6)	130 (6.6)	NA	NA	NA
Eclampsia	1 (0.1)	1 (0.1)	NA	NA	NA
HELLP syndrome	2 (0.2)	2 (0.1)	NA	NA	NA
Small-for-gestational age birth weight ^d	107 (10.6)	178 (9.1)	1.19 (0.92-1.52)	1.16 (0.89-1.50)	1.31 (0.97-1.77)
Stillbirth	2 (0.2)	3 (0.2)	1.29 (0.17-7.82)	NA	NA

35% RSVpreF vaccination rate

Incidence of preterm births among singleton pregnancies in the VSD reaching specified gestational ages from 22–36 weeks during 2017–2022



10,295 vaccines
4.1% PTB incidence
Within expected range

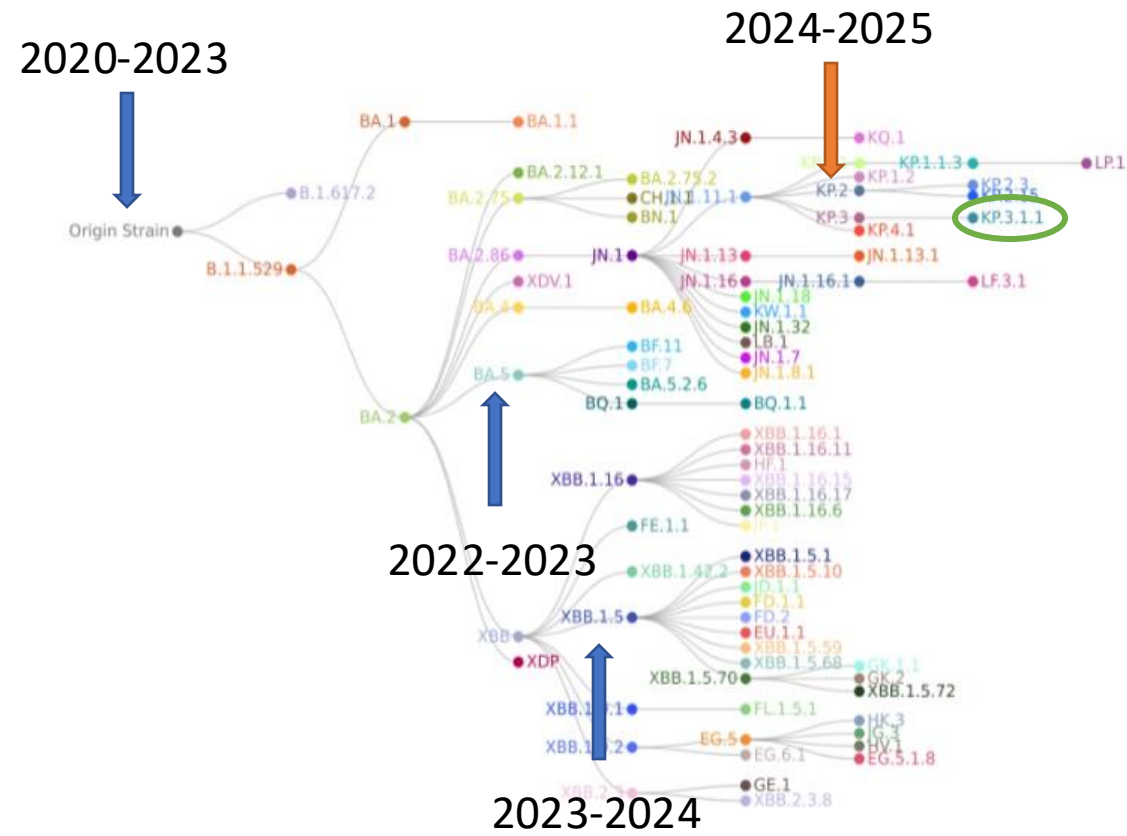
No verified reports of Guillain Barré syndrome

Son et al. JAMA Netw Open. 2024. PMID: 38976271

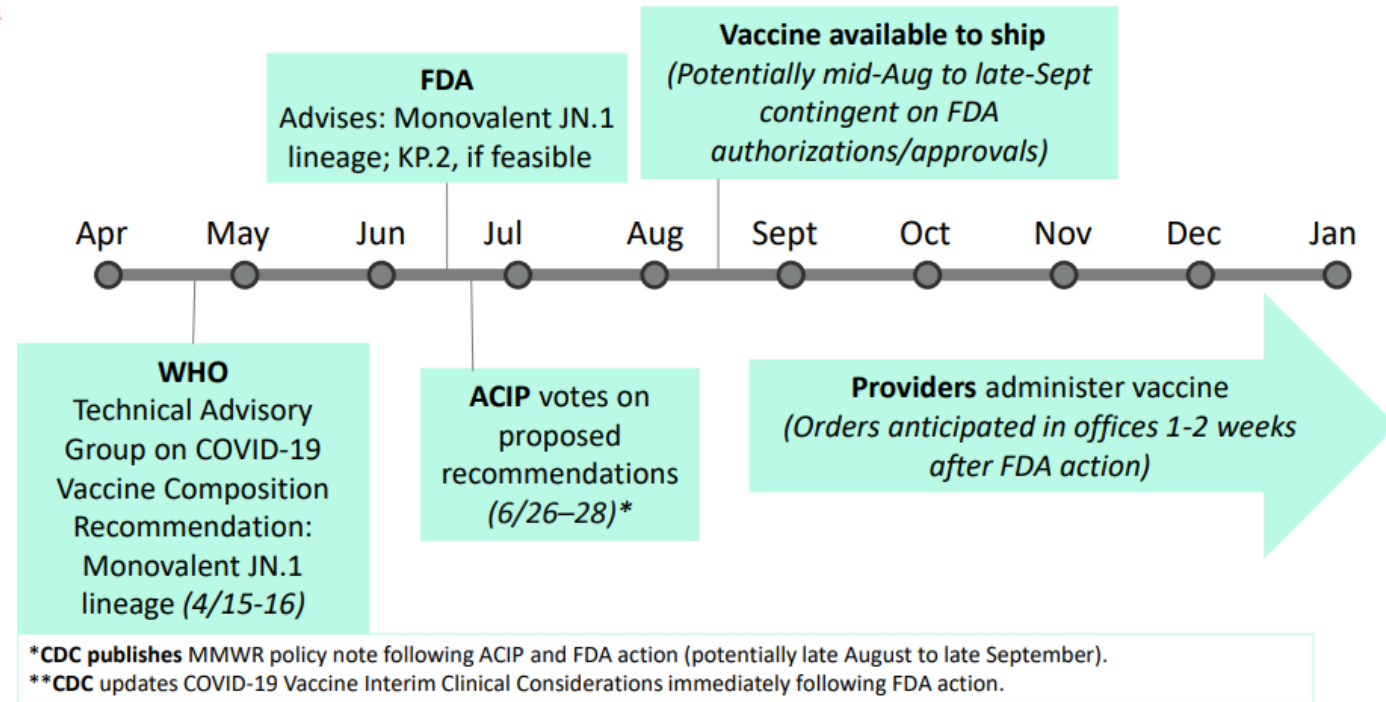
<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2024-06-26-28/03-RSV-Mat-Peds-Moro-508.pdf>

COVID-19: yes, we are still talking about this!

COVID-19 deaths continue to fall, but still more deadly than flu



Prospective 2024 COVID-19 vaccine timeline

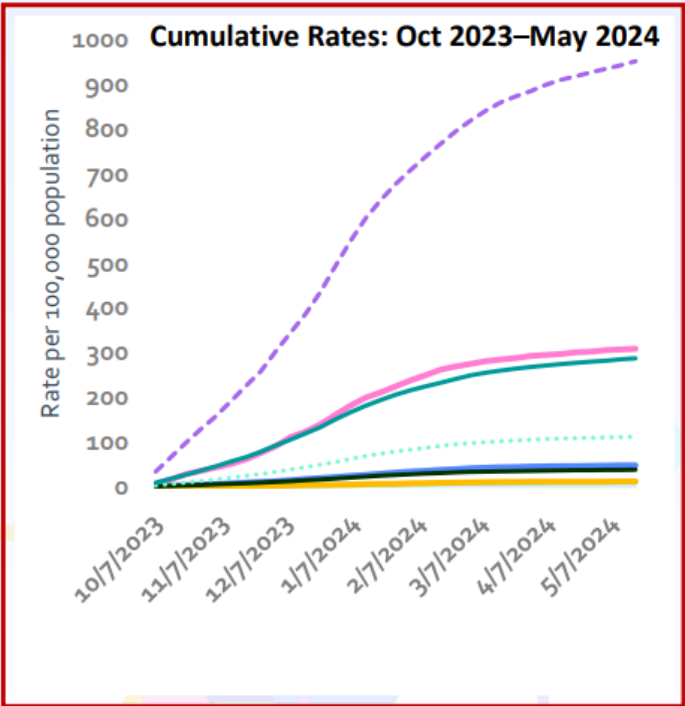
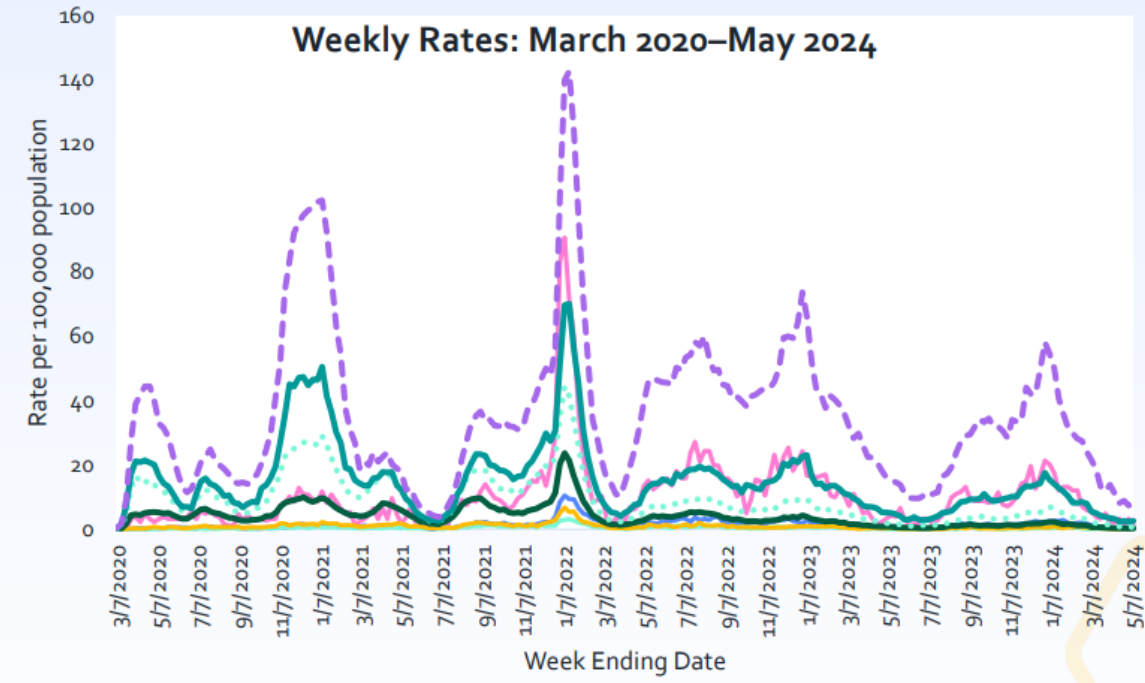


<https://covid.cdc.gov/covid-data-tracker/#variant-proportions>

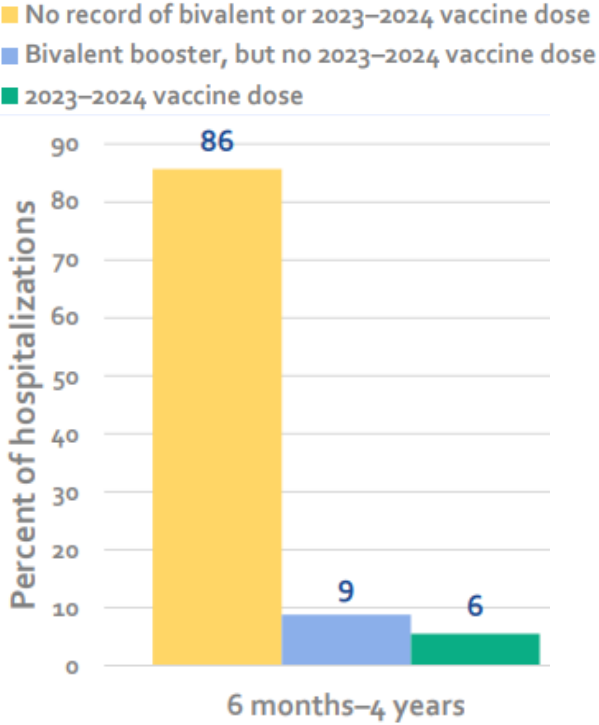
<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2024-06-26-28/07-COVID-Stokely-508.pdf>

COVID-NET US data still demonstrate second most hospitalizations in the infants <6 months old– the age where passive immunity from maternal immunization is most important

- 75% have no underlying medical conditions; majority missed 2023-24 booster



Rates highest in ≥75 years, followed by infants <6 months and adults 65–74 years



Pregnant people and children were largely undervaccinated in the 2023-2024 season

- 2023-2024 COVID-19 XBB.1.5 vaccination rates were <25% in pregnant individuals
- <7% for children 6-23 months old

Figure 2. Percent of pregnant persons ages 18–49 years who received an updated 2023-24 COVID-19 vaccine overall and by race and ethnicity — Vaccine Safety Datalink

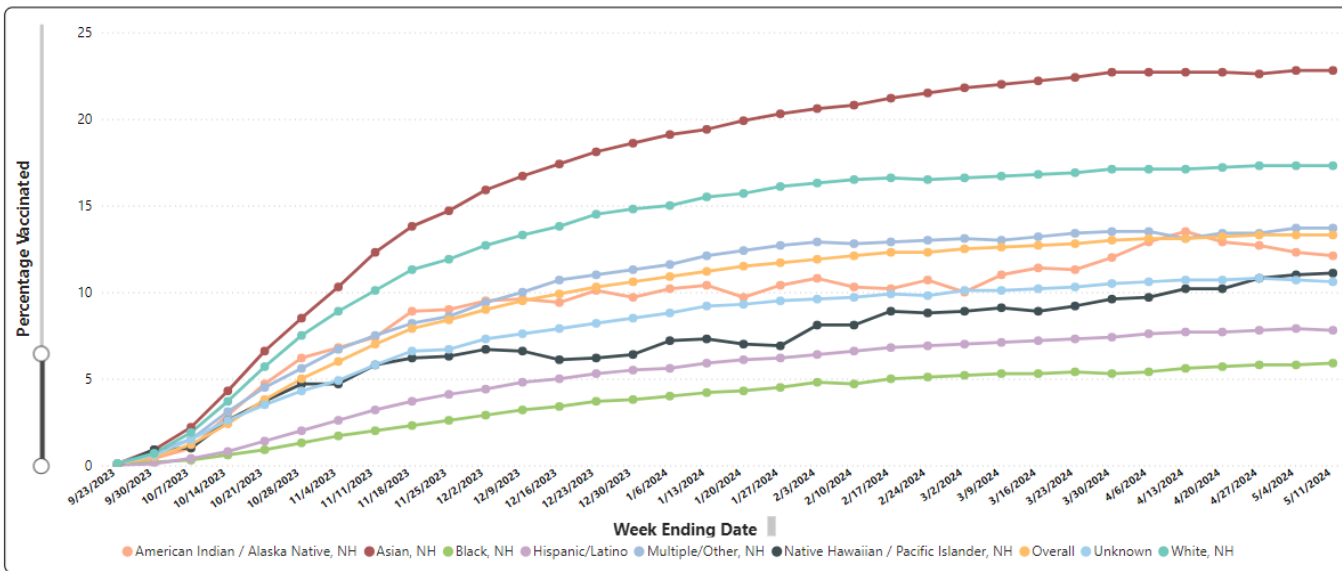
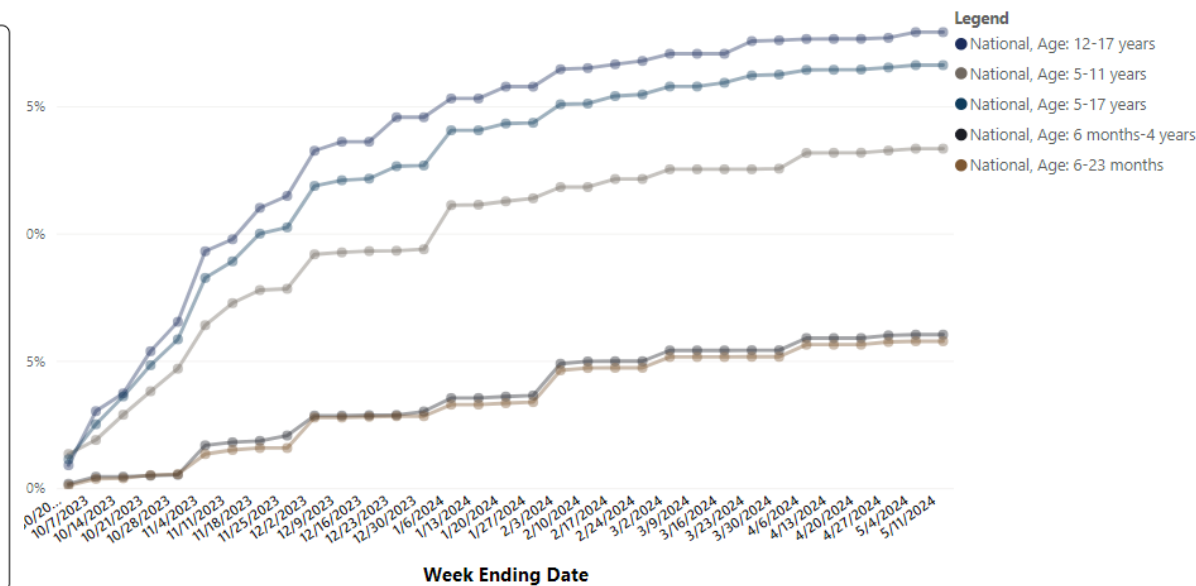


Figure 1A. Cumulative Percentage of Children 6 Months-17 Years Who Are Up to Date with the Updated 2023-24 COVID-19 Vaccine^{†,‡}.
Data Source: National Immunization Survey



<https://www.cdc.gov/vaccines/imz-managers/coverage/covidvaxview/interactive/pregnant-coverage-vaccination.html>

<https://www.cdc.gov/vaccines/imz-managers/coverage/covidvaxview/interactive/children-coverage-vaccination.html>

COVID-19 2023-24 vaccine boosters were effective at reducing emergency room and urgent care visits in children

VISION: VE of 2023–2024 COVID-19 vaccine doses against ED/UC encounters was similar across age groups September 2023 – May 2024

Age group COVID-19 vaccination status	Total encounters	SARS-CoV-2-test-positive, N (%)	Median interval since last dose among those vaccinated, days (IQR)	Adjusted VE (95% CI)	
No updated 2023-2024 COVID-19 vaccine dose*					
9 months-4 years	30,286	1,180 (4)	349 (236-443)	Ref	
5-17 years	37,203	1,449 (4)	650 (449-769)	Ref	
18-64 years	148,273	15,100 (10)	751 (573-887)	Ref	
≥65 years	59,422	7,430 (13)	609 (399-803)	Ref	
2023-2024 COVID-19 dose received 7-59 days earlier					
9 months-4 years	613	10 (2)	33 (19-46)	66 (36-82)	1wk-2mo
5-17 years	805	11 (1)	33 (19-47)	71 (47-84)	
18-64 years	5,137	313 (6)	34 (20-47)	53 (47-58)	
≥65 years	8,007	669 (8)	35 (21-47)	47 (42-51)	
2023-2024 COVID-19 dose received 60-179 days earlier					
9 months-4 years	706	14 (2)	104 (80-137)	24 (-31-56)**	2mo-6mo
5-17 years	1,343	22 (2)	111 (86-138)	50 (22-68)	
18-64 years	8,559	506 (6)	108 (82-137)	24 (17-31)	
≥65 years	16,106	1,232 (8)	111 (84-142)	25 (20-30)	

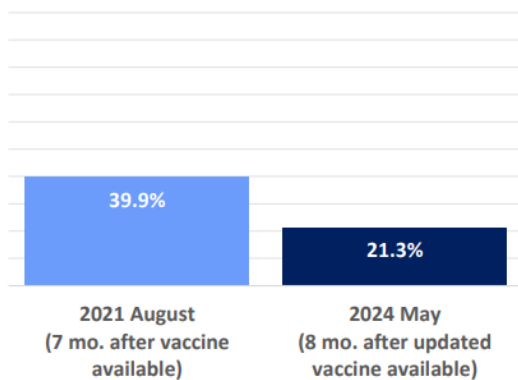
* Includes all individuals who did not receive a 2023-2024 COVID-19 vaccine. For those aged ≥5 years, this includes unvaccinated persons and persons who were vaccinated with ≥1 original monovalent or bivalent COVID-19 doses. For those aged <5 years, both those in the referent group and those in the vaccinated group were required to have completed an initial series. The 2023-2024 dose could have been part of the initial series or in addition to the initial series.

** 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.

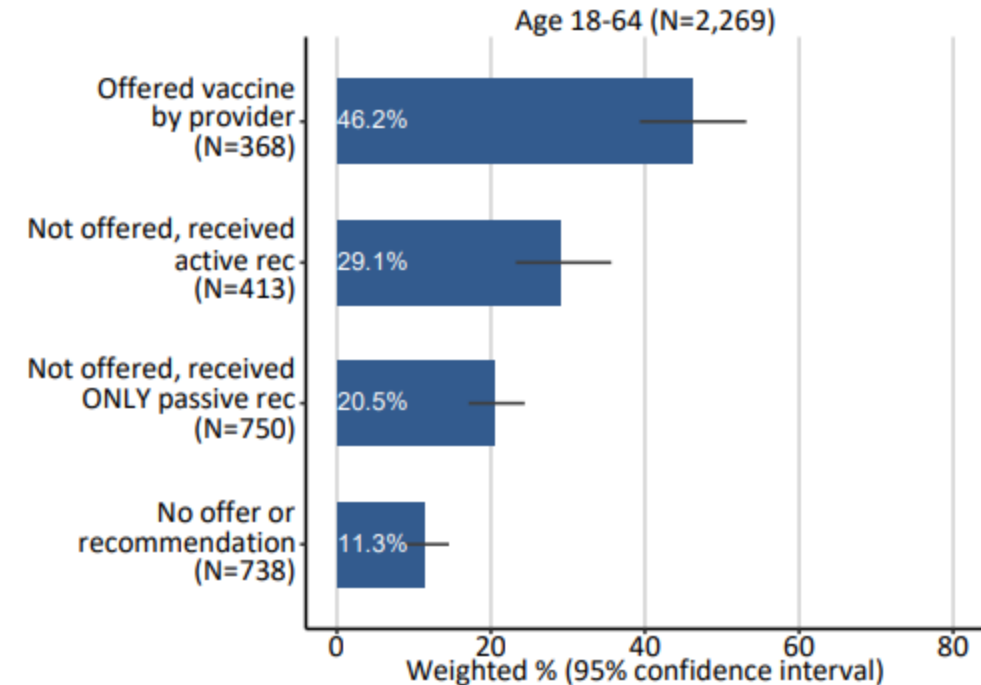
Active recommendation of vaccination by healthcare providers enhances uptake; and so does clinic administration

Healthcare provider COVID-19 vaccine recommendations, NIS-ACM

Percent of adults whose healthcare provider recommends COVID-19 vaccine



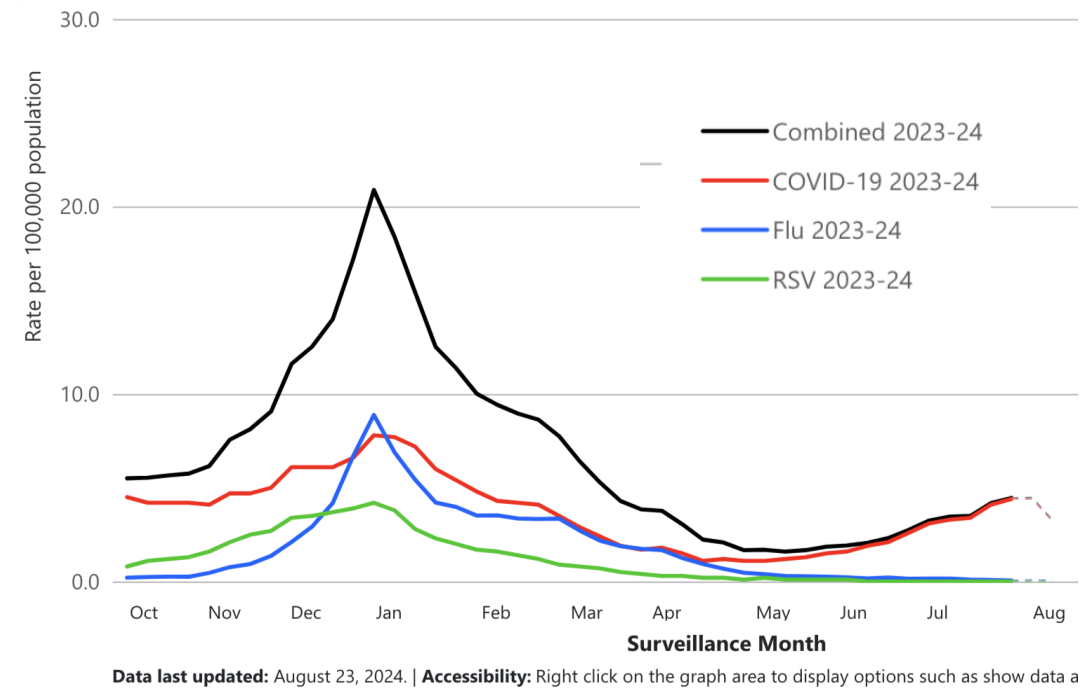
Relative to 2021, adults reported **fewer providers are recommending COVID-19 vaccines.**



Data source: National Immunization Survey – Adult COVID Module [About the National Immunization Surveys | CDC](#)

Resource for finding vaccine sites: [Vaccines.gov](https://www.vaccines.gov)

Summary of Findings and Recommendations



- Maternal and infant immunizations had favorable safety and efficacy profiles regionally, nationally, and internationally
- There were barriers to implementation, but we have strategies to improve this season
- Providers should *actively* recommend vaccines for pregnant people and infants
- Provide vaccines in clinic where possible
- Provide infant immunization in birth hospitalization