Vaccines for Pregnant People

2024 Immunization Summit

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Life or death for a young child too often depends on whether he or she is born in a country where vaccines are available or not.

Nelson Mandela

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Disclosures

- Christiana Receives Revenue from the NIH RECOVER Initiative

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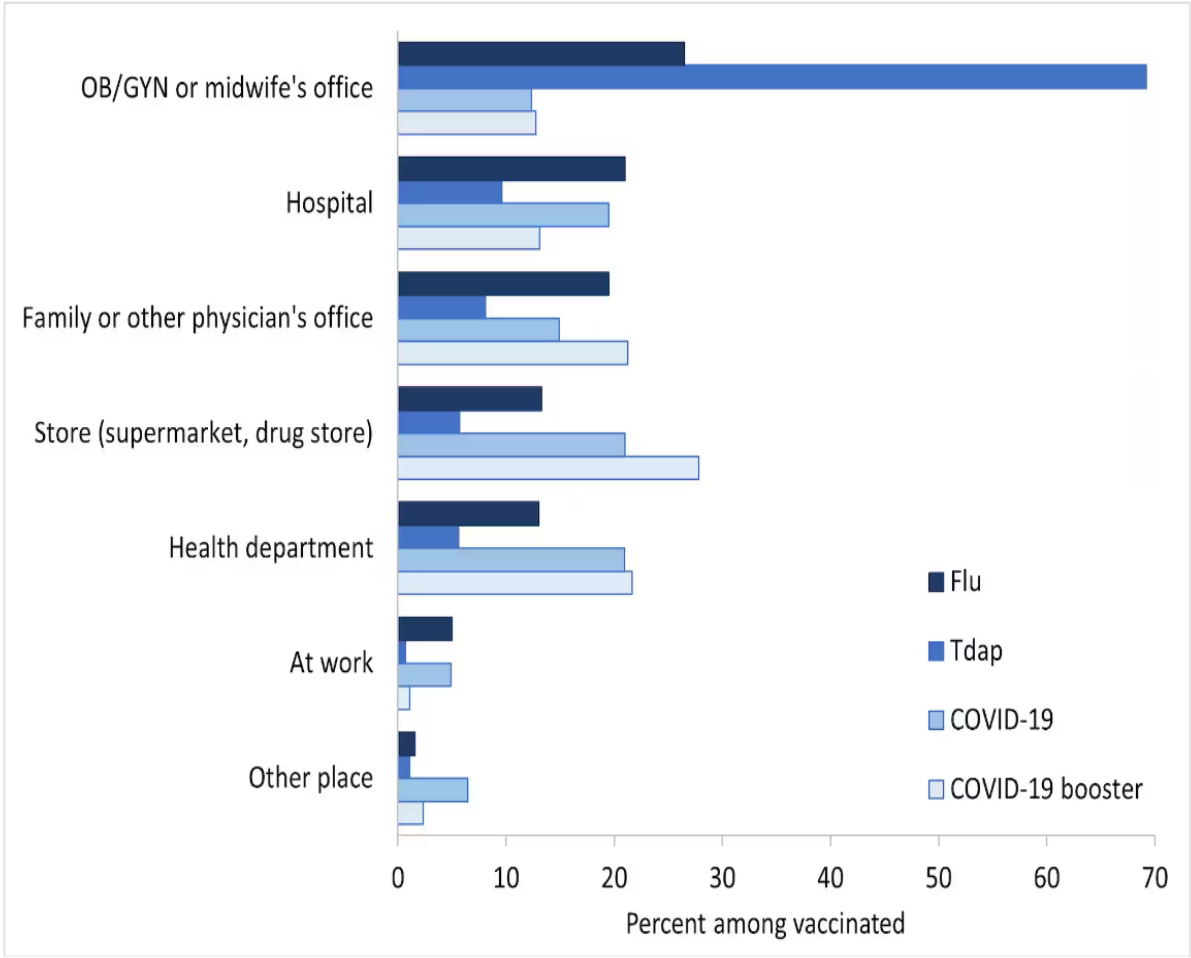
Overview Update

- OB/Gyn's as immunizers
- Influenzae
- TDAP
- Covid
- RSV
  - Maternal Immunization
  - Monoclonal Antibodies

Ob/Gyn as Vaccinators

- Often serve as primary care for women
- Pregnancy is a window of medical re-engagement
  - Vaccines are often viewed through the lens of Newborn benefit



2021-2022 Source of Vaccine for Pregnant People

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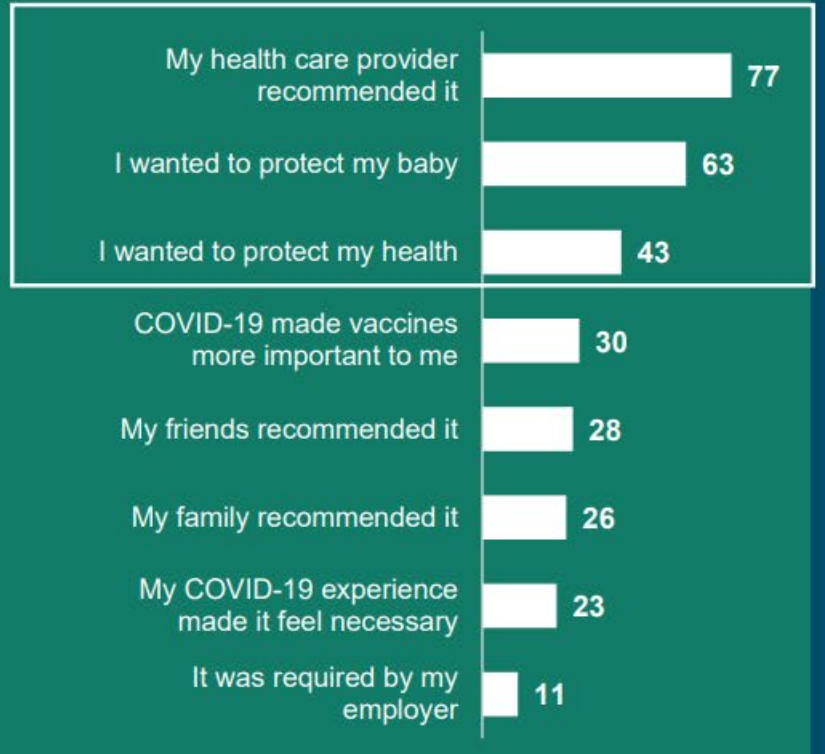
Health care providers' recommendations and a desire to protect the baby's health drive vaccine decisions

Please rank the top 3 reasons for getting a flu/Tdap/COVID-19 vaccine during pregnancy. Tdap *n*=274; Flu *n*=167; COVID-19 *n*=101

Top Reasons for Getting Tdap Vaccine

(Percent Ranked Top 3)

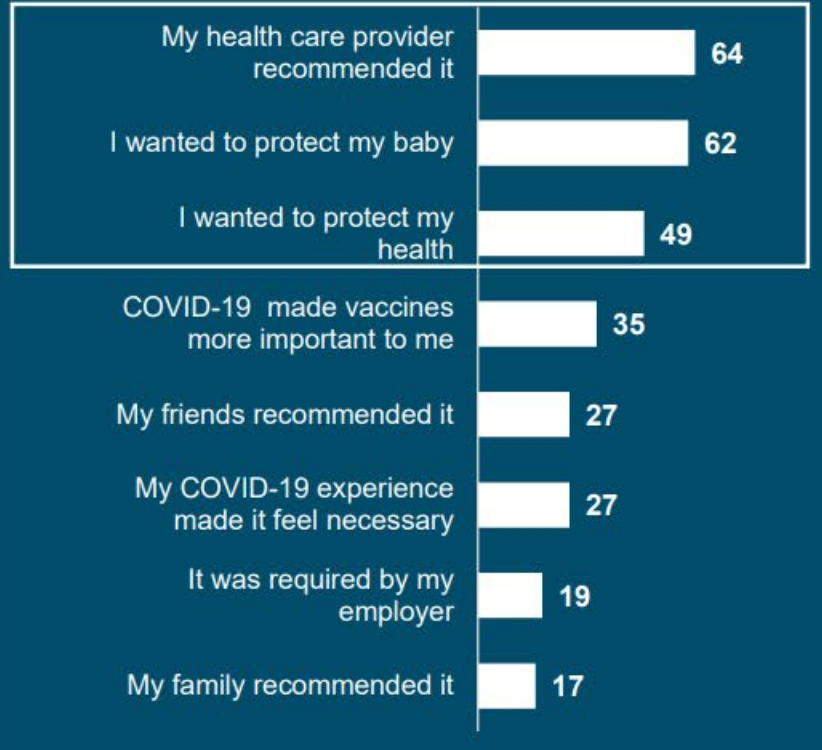
Sub-sample who received Tdap vaccine before or during pregnancy



Top Reasons for Getting Flu Vaccine

(Percent Ranked Top 3)

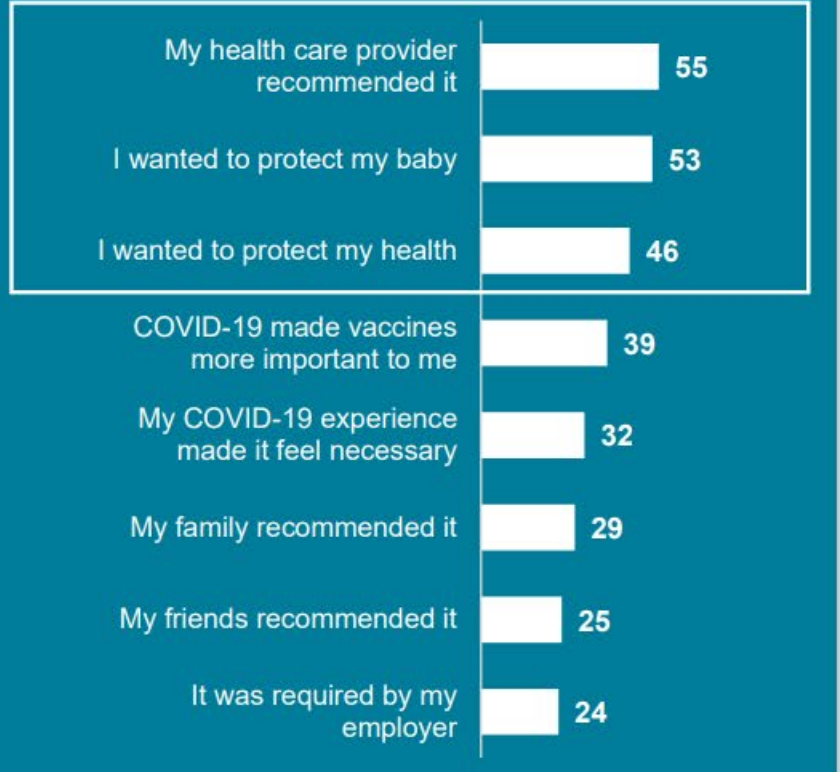
Sub-sample who received flu vaccine before or during pregnancy



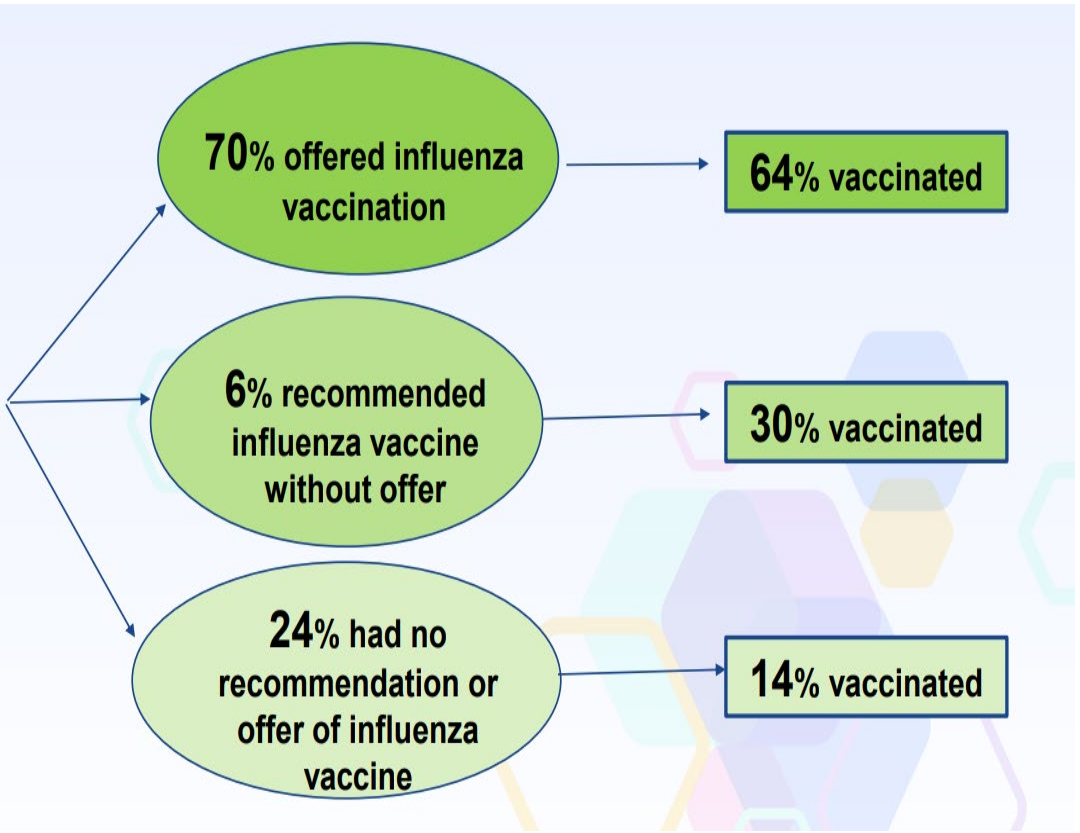
Top Reasons for Getting COVID-19 Vaccine

(Percent Ranked Top 3)

Sub-sample who received COVID-19 vaccine before or during pregnancy



Key to success is making it easy



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Key counselling points

- Qualitative research continues to emphasize:
  - Vaccines are safe/beneficial pregnancy
  - Reluctance about long-term safety (COVID-19)
  - Concerns about fever in first trimester and pregnancy loss
  - Potential for increased maternal side effects due to being pregnant

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Maternal Influenzae

- Maternal-
  - Physiologic changes during pregnancy increase the risk of severe disease and death (5x-mostly 2nd and 3rd Trimester)*
  - Associated with a higher rate of preterm birth(aHR 1.30 95%CI 1.01-4.41)
- Neonatal Influenza
  - No infant vaccine until 6-months of age
  - Infants are at high risk of hospitalization and death from Influenzas**

*Grohskopf LA,. MMWR (2021)
**Frawley BJOG 2024
**Epperson S et al MMWR (2014)

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Does Influenzae vaccination work in pregnancy?

- RCT of 340 pregnancies randomized to Flu Vaccine
- Vaccine Efficacy of 63%
  - Infants 29%
  - Mothers 36%

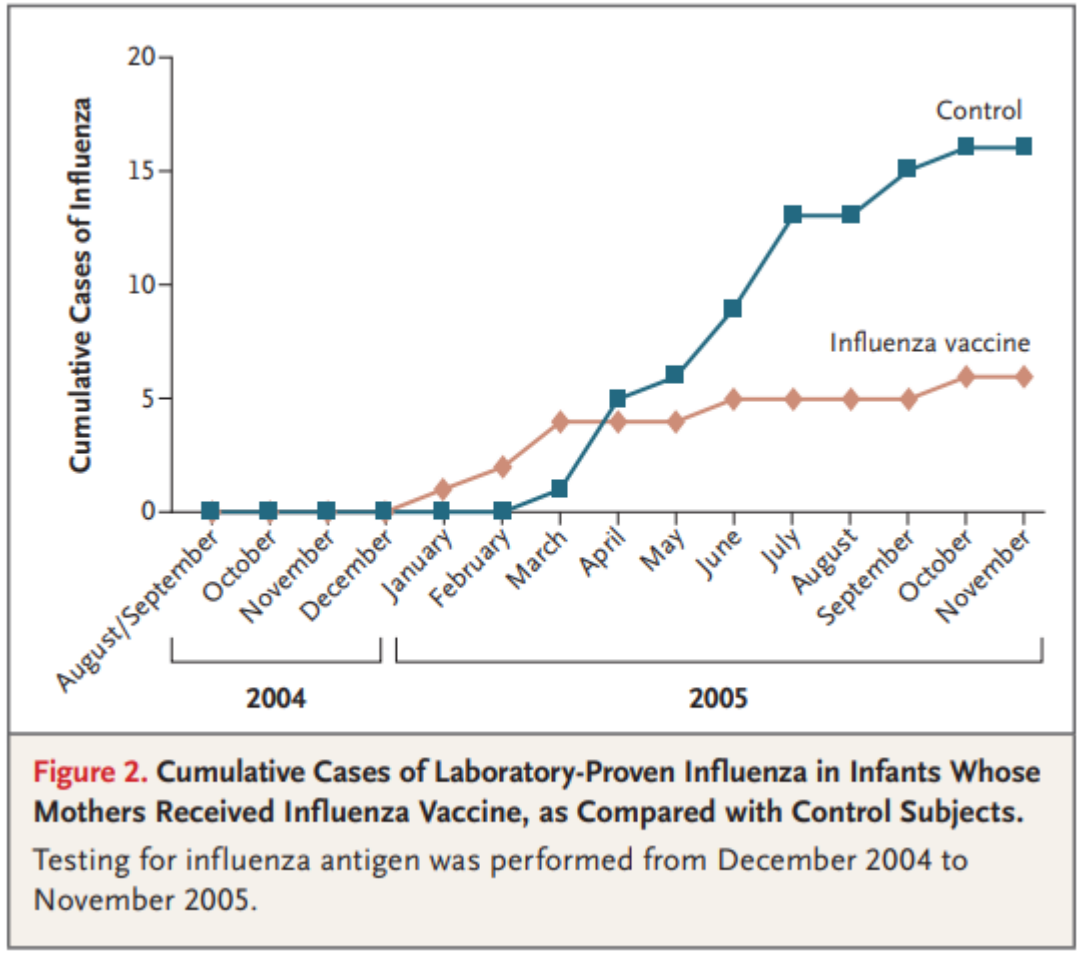

Figure 2. Cumulative Cases of Laboratory-Proven Influenza in Infants Whose Mothers Received Influenza Vaccine, as Compared with Control Subjects.
Testing for influenza antigen was performed from December 2004 to November 2005.

N Engl J Med 2008;359:1555-1564

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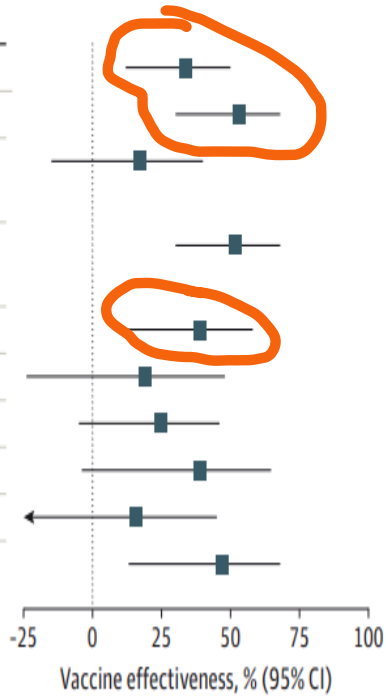
Does Influenzae vaccination work in pregnancy?

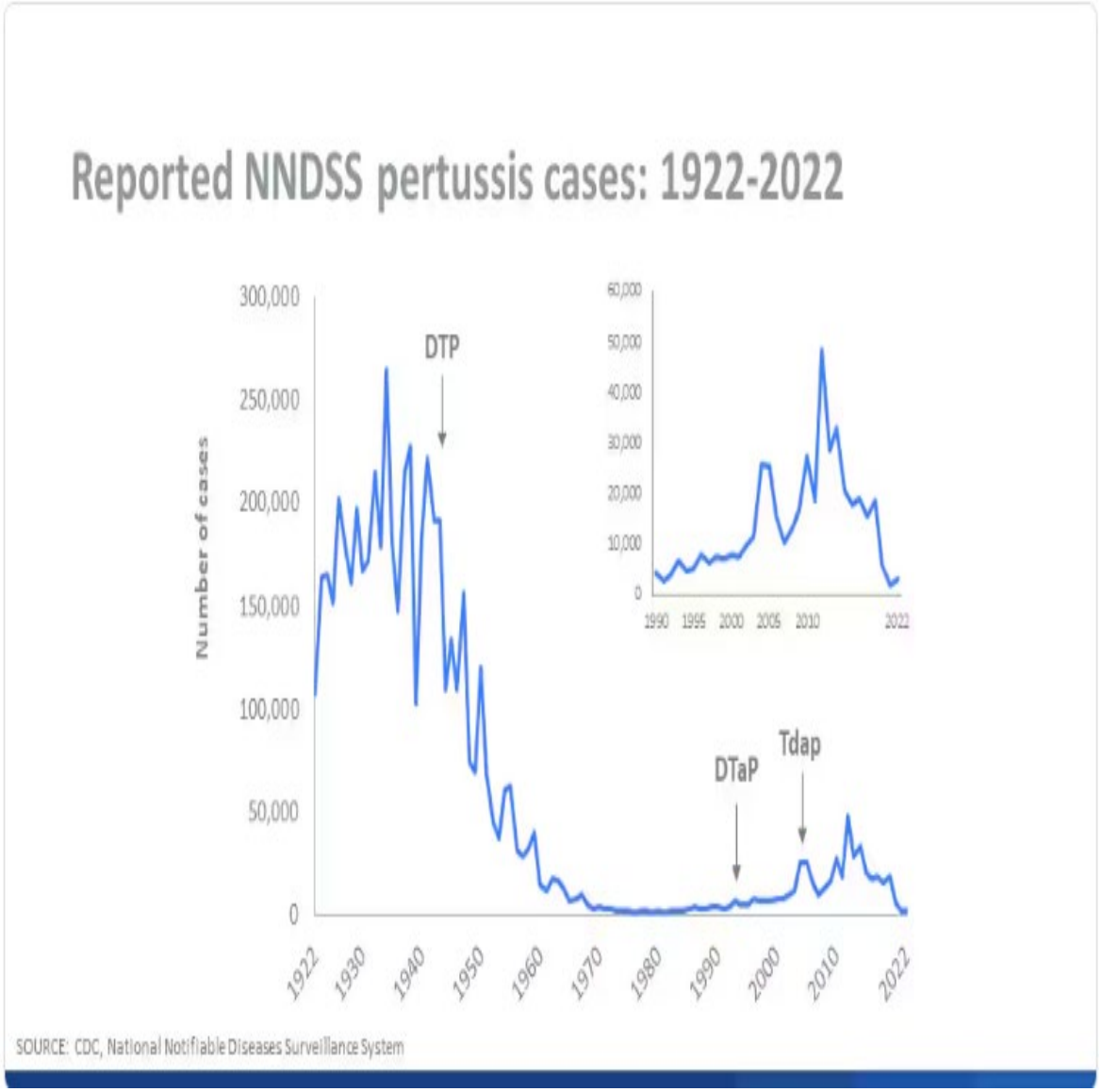
- 2016-2020 flu seasons
- ED visits of infants<6 months
- Vaccination needed to be >14 days from delivery

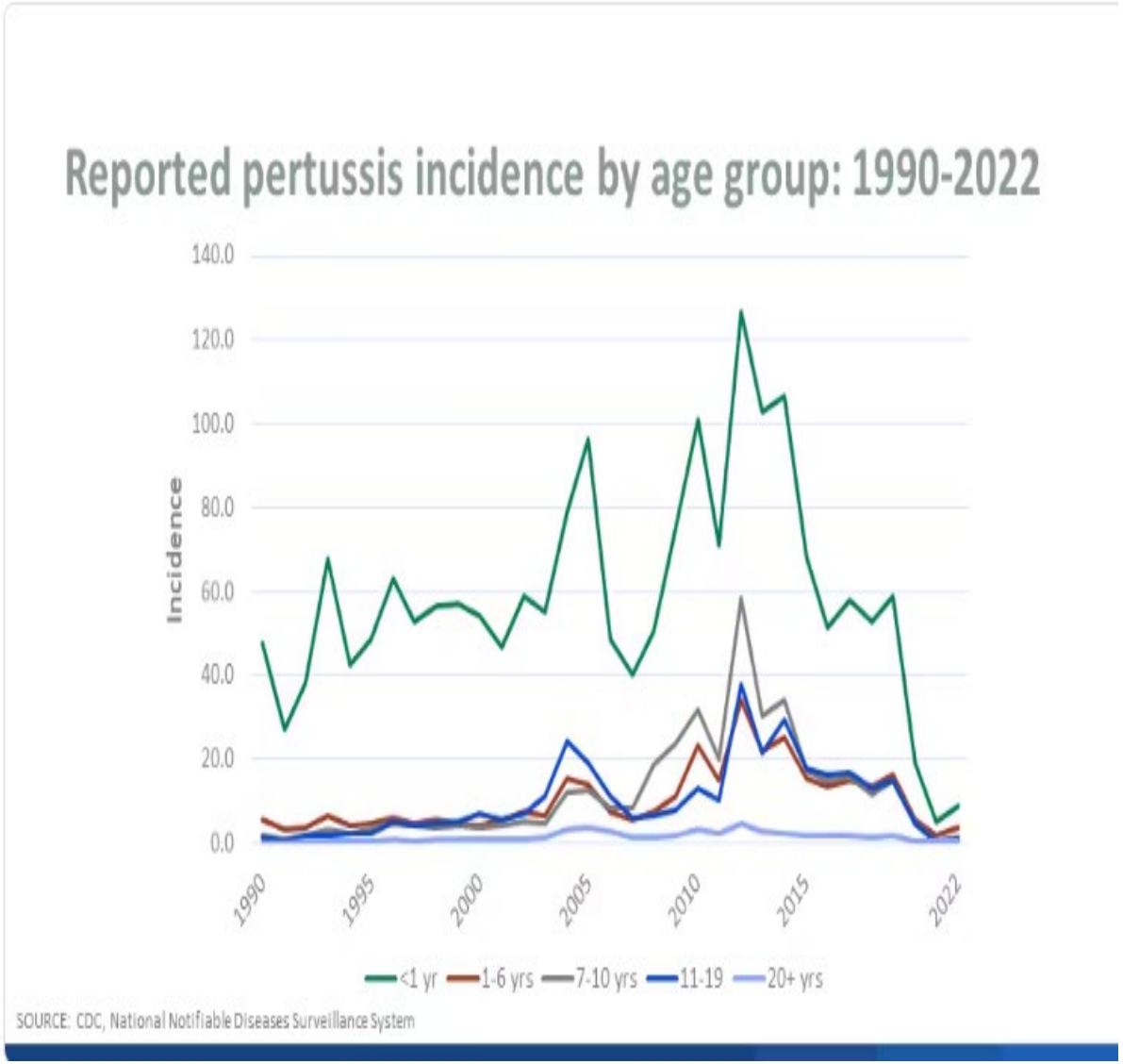
Figure 2. Effectiveness of Maternal Influenza Vaccination During Pregnancy Against Influenza Hospitalizations and Emergency Department (ED) Visits in Infants

Infants <6 mo of age	Vaccinated mothers, No./total No. (%)		Effectiveness of maternal vaccination against influenza illness in infants, % (95% CI)
	Infants with influenza illness	Control infants	
Overall effectiveness of maternal vaccination	94/223 (42)	1913/3541 (54)	34 (12 to 50)
Infants <3 mo of age	49/106 (46)	1293/2147 (60)	53 (30 to 68)
Mother vaccinated during first or second trimester of pregnancy	59/188 (31)	1009/2637 (38)	17 (-15 to 40)
Mother vaccinated during third trimester of pregnancy	35/164 (21)	904/2532 (36)	52 (30 to 68)
Hospital admission	55/125 (44)	1416/2541 (56)	39 (12 to 58)
ED visit	39/98 (40)	497/1000 (50)	19 (-24 to 48)
Influenza A	70/157 (45)	1913/3541 (54)	25 (-5 to 46)
H1N1	21/53 (40)	1913/3541 (54)	39 (-4 to 65)
H3N2	42/87 (48)	1913/3541 (54)	16 (-29 to 45)
Influenza B	25/67 (37)	1913/3541 (54)	47 (13 to 68)



Pertussis Incidence





Pertussis

- Humans are the only reservoir
- Pertussis has been seen highest in the period between birth and 6-8 weeks of age
- >90% of infants under 2 months with pertussis infection are hospitalized
- 76% of pertussis related deaths occur in infants aged under 2 months
- Child Vaccination starts at age 2 months

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Pertussis vaccination in pregnancy-2011

- Optimal timing of TDAP immunization is 27-36 weeks
- Given every pregnancy
- Questions about can a Pertussis only vaccine be developed
- FDA approved use of Tdap among pregnant people to prevent pertussis in infants <2months old in Oct 2022 (Boostrix) and Jan 2023 (Adacel)

- Source: Liang JL, Tiwari T, Moro P, et al. Prevention of Pertussis, Tetanus, and Diphtheria with Vaccines in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep 2018;67(No. RR-2):1–44. DOI: http://dx.doi.org/10.15585/mmwr.rr6702a1.

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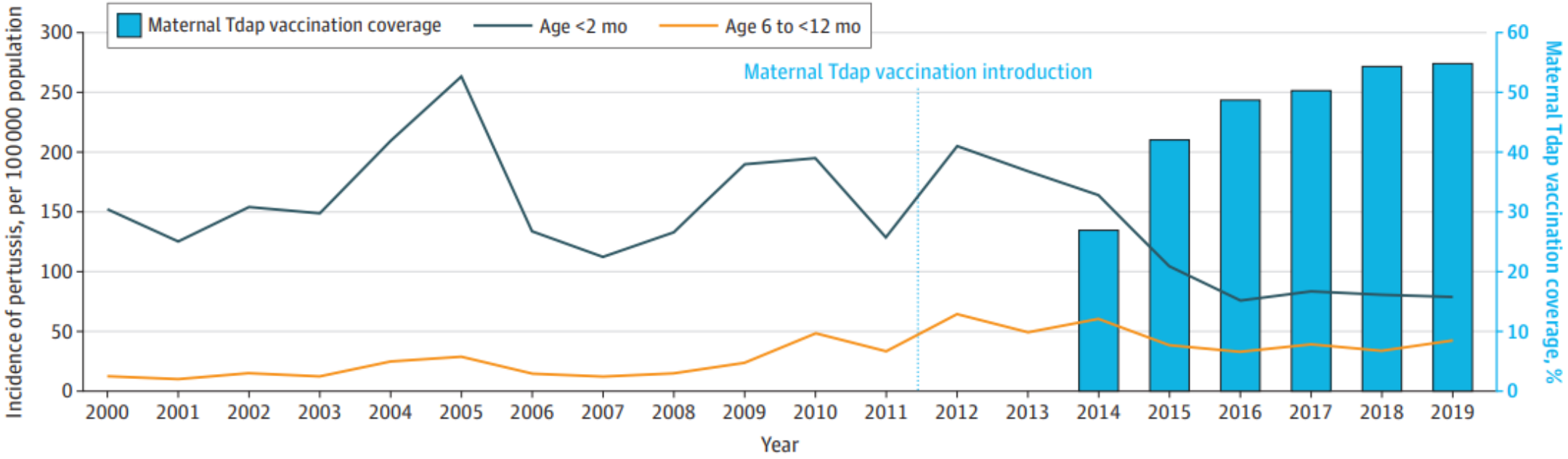
Efficacy of Maternal Vaccination for Pertussis

Figure 1. Annual Incidence of Reported Pertussis Among Infants Younger Than 2 Months and Infants Aged 6 Months to Less Than 12 Months, 2000-2019



Skoff JAMA Pediatrics 2023

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TDAP effectiveness

TABLE 2 VE of Maternal Tdap and Infant DTaP Vaccination in Preventing Pertussis in 148 981 Newborns in the Study Population Followed From Birth Until 2 and 12 Months of Age

	2-mo Follow-up (Total Pertussis Cases = 17)				12-mo Follow-up (Total Pertussis Cases = 103)			
	No. of Pertussis Cases (Rate per 100 000 Person-Years)		VE, % (95% CI)	*P*	No. of Pertussis Cases (Rate per 100 000 Person-Years)		VE, % (95% CI)	*P*
Timing of maternal Tdap vaccination	No maternal Tdap	Maternal Tdap			No maternal Tdap	Maternal Tdap		
During pregnancy (8+ days before birth)[a]	15 (112.7)	1 (8.7)	91.4 (19.5 to 99.1)	.032	80 (109.1)	22 (38.0)	69.0 (43.6 to 82.9)	<.001
Before pregnancy	15 (79.4)	2 (32.5)	68.6 (−44.9 to 93.2)	.138	89 (89.4)	14 (42.4)	55.9 (20.7 to 75.5)	.006
After pregnancy	13 (59.3)	4 (129.4)	45.7 (−88.2 to 84.3)	.336	80 (72.1)	23 (106.2)	24.4 (−27.8 to 55.3)	.296
Infant DTaP vaccination								
First dose	—	—	—	—	—	—	48.2 (−6.4 to 74.8)	.073
Second dose	—	—	—	—	—	—	64.2 (17.9 to 84.4)	.015
Third dose	—	—	—	—	—	—	86.8 (69.2 to 94.4)	<.001

Baxter R, Pediatrics. 2017 May;139(5):

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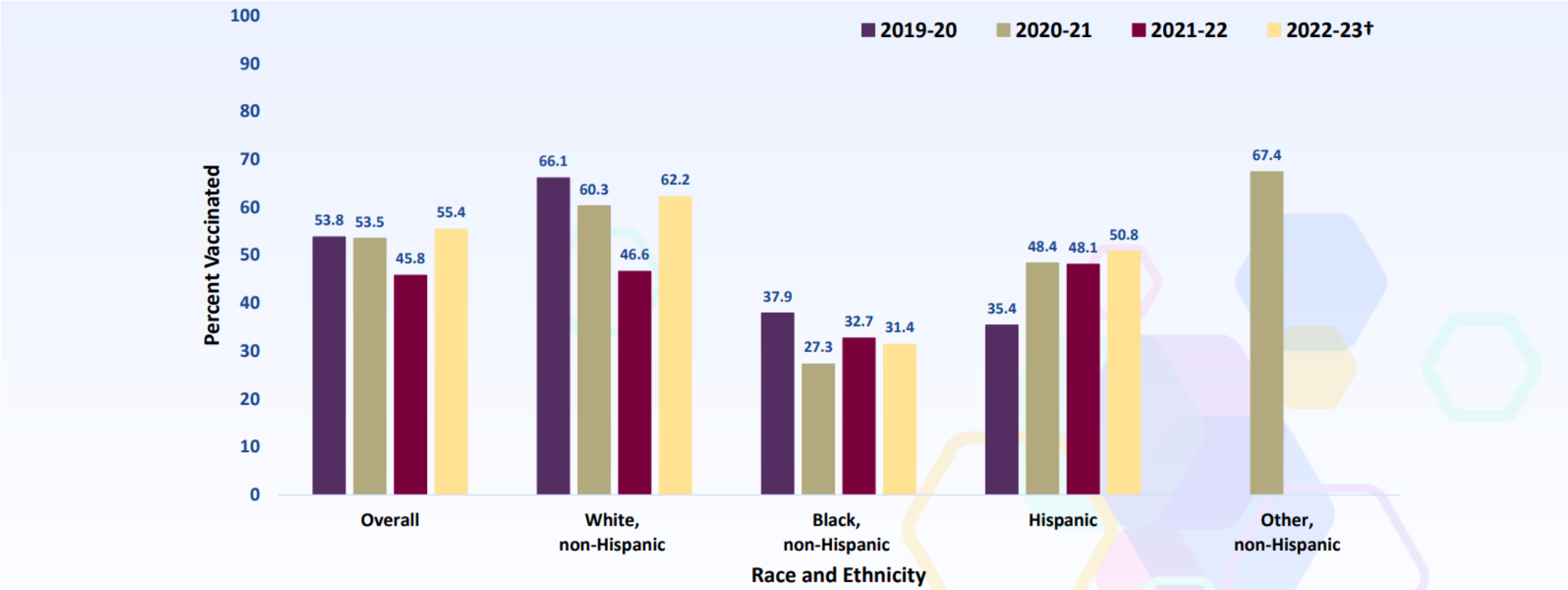
TDAP Coverage of pregnant People by Race & Ethnicity



NOTE: Estimates that met suppression criteria are not presented.

*Women who reported a pregnancy since August 1 of each season who had a live birth by the time of the survey and were vaccinated during most recent pregnancy were counted as vaccinated.

†The estimates for 2022-23 season are preliminary and have not been published.

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COVID Pregnancy

- Clear data that pregnant people were more likely to be hospitalized and susceptible-Increase in Stillbirths & PTB

Table 5 | Preterm births to women admitted to hospital with symptomatic SARS-CoV-2 by dominant variant period and severity of maternal infection, March 1, 2020, to March 31, 2022, United Kingdom

SARS-CoV-2 dominant variant	Wild-type period		Alpha period		Delta period		Omicron period	
Severity[a]	Mild (*N* = 1067)	Moderate to severe[a] (*N* = 370)	Mild (*N* = 1220)	Moderate to severe[a] (*N* = 678)	Mild (*N* = 1420)	Moderate to severe[a] (*N* = 1055)	Mild (*N* = 1098)	Moderate to severe[a] (*N* = 208)
Preterm live birth[e] - no. (%)								
<34 weeks' GA	56 (5.3)	57 (15.5)	56 (4.6)	121 (18.1)	92 (6.5)	177 (16.9)	41 (3.7)	17 (8.2)
Model 1[b]: RR (95% CI)	[Ref]	3.74 (2.52–5.55)	0.87 (0.59–1.27)	4.41 (3.15–6.17)	1.27 (0.90–1.79)	4.26 (3.10–5.85)	0.69 (0.46–1.04)	1.83 (1.04–3.24)

Table 7 | Perinatal outcomes in births to women with symptomatic SARS-CoV-2 admitted to hospital by number of documented maternal vaccination doses, from January 1, 2021, to March 31, 2022, United Kingdom

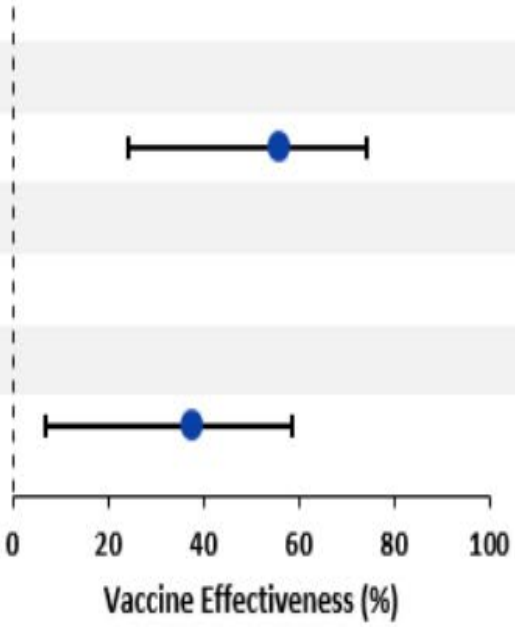
Vaccination status	Unvaccinated (*N* = 3184)	Vaccine status unknown (*N* = 1275)	1 dose (*N* = 347)	2 doses (*N* = 319)	3 doses (*N* = 60)
Stillbirth - no. (%)	64 (2.0)	19 (1.5)	3 (0.9)	5 (0.6)	0
Preterm births[a] - no. (%)					
<34 weeks	299 (9.5)	123 (9.7)	13 (3.8)	20 (6.3)	3 (5.0)
34^{+0} –36^{+6} weeks'	443 (14.0)	152 (12.0)	34 (9.9)	26 (8.2)	7 (11.7)
Admission to Neonatal Unit[b]- no. (%)	620 (19.9)	270 (21.5)	40 (11.7)	40 (12.7)	9 (15.0)
Neonatal Death[c] - no. (%)	6 (0.2)	3 (0.2)	2 (0.6)	1 (0.3)	0

[a]45 infants born to symptomatic women had missing data for gestational age at birth.
[b]112 infants born to symptomatic women had missing data for admission to neonatal unit.
[c]77 infants born to symptomatic women had missing data for neonatal death.

Nat Commun **15**, 3234 (2024)

Covid Immunization in Pregnancy

Vaccination during pregnancy*	Total	Case infants, N (%)	Median interval since last maternal dose, days (IQR)	Infant median age at hospitalization, days (IQR)	Adjusted VE (95% CI)	Effectiveness of Maternal Vaccination against Infant Covid-19 Hospitalization % (95% CI)†
Infants <3 months of age at hospitalization						
Unvaccinated (ref)	310	174 (56)	NA	44 (27 to 63)	Ref	
Vaccinated	101	43 (43)	222 (152 to 271)	41 (23 to 66)	56 (24 to 75)*	
Infants < 6 months of age at hospitalization						
Unvaccinated (ref)	498	281 (56)	NA	68 (37 to 125)	Ref	
Vaccinated	163	78 (48)	236 (190 to 302)	74 (33 to 132)	38 (7 to 59)*	



CDC Unpublished Data

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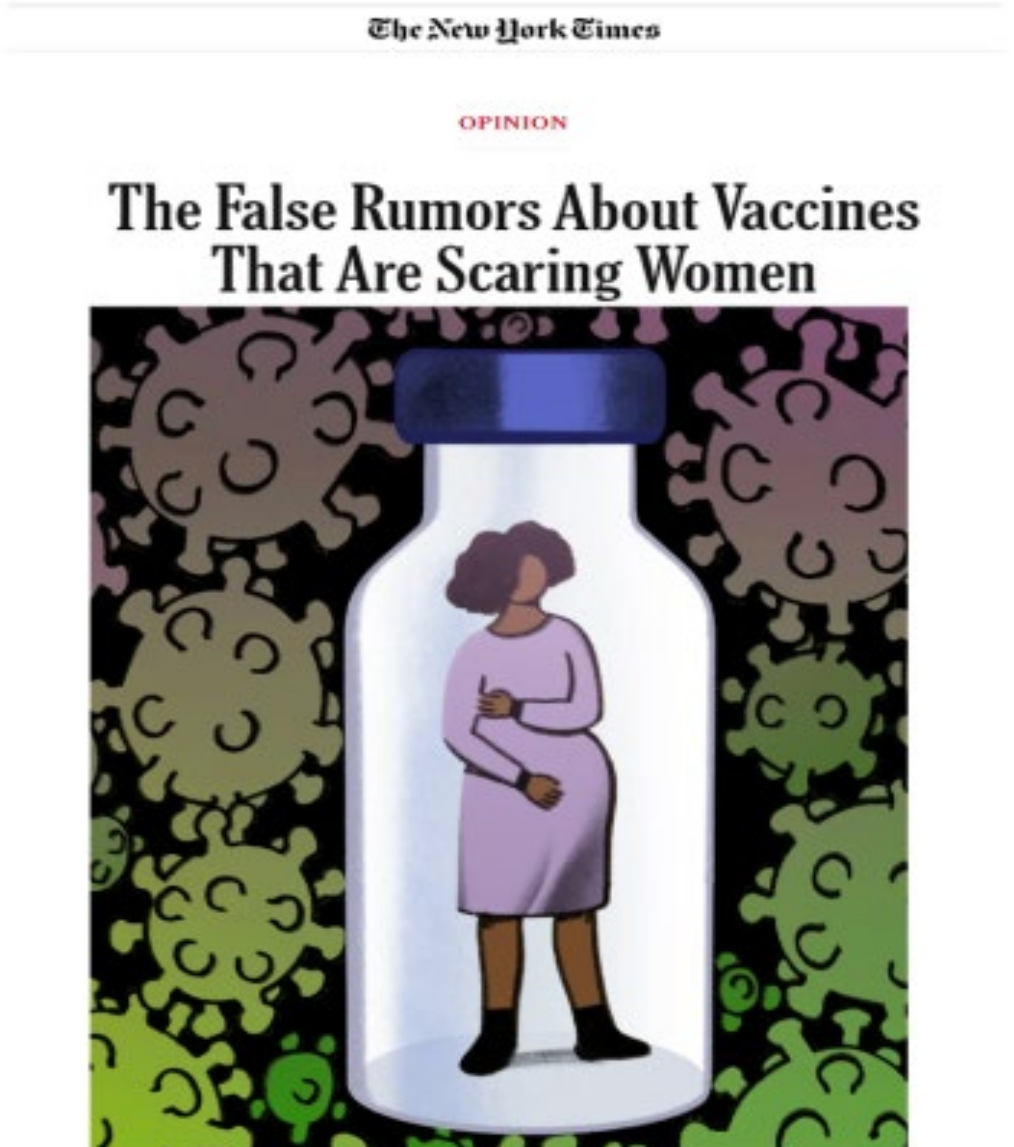
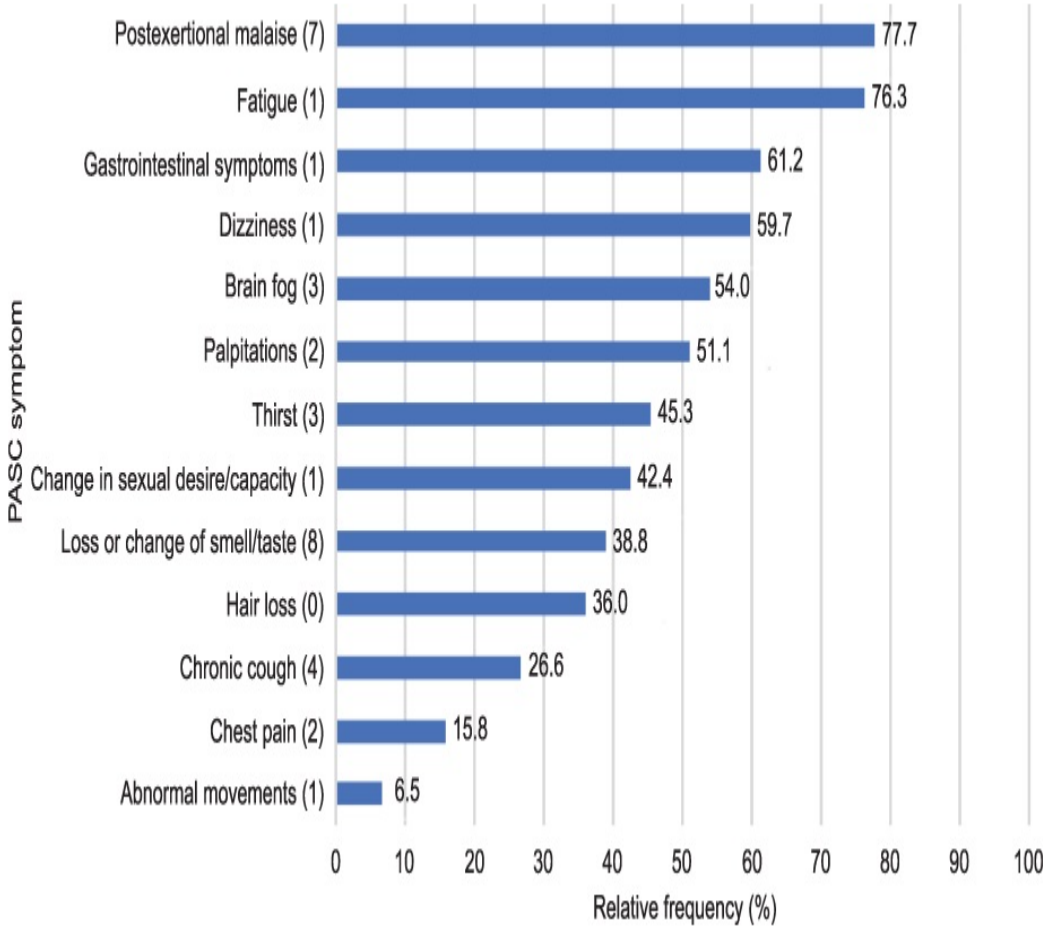
Covid Vaccine Hesitancy

- Social Media
- Concerns about stillbirth/miscarriage/ PTB and fertility
- Lack of inclusion of pregnant women in initial trials



Long Covid in Pregnancy

- NIH Recover study
- 1,502 participants- 61.1% Omicron, 51.4% had been vaccinated
- 9.3% had at 10.3 months
- Can no longer find negative controls



Obstetrics & Gynecology 144(3):p 411-420, September 2024.

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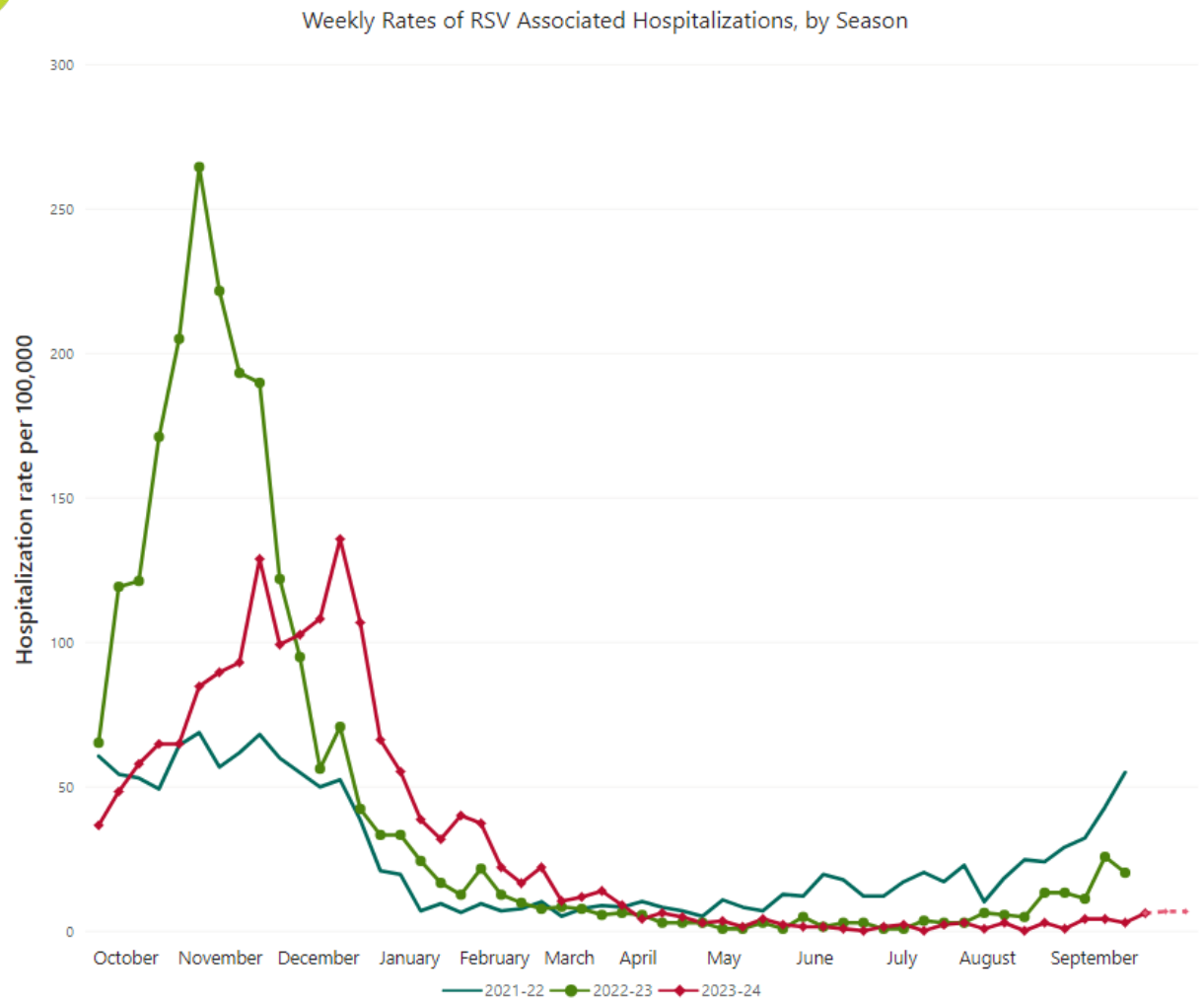
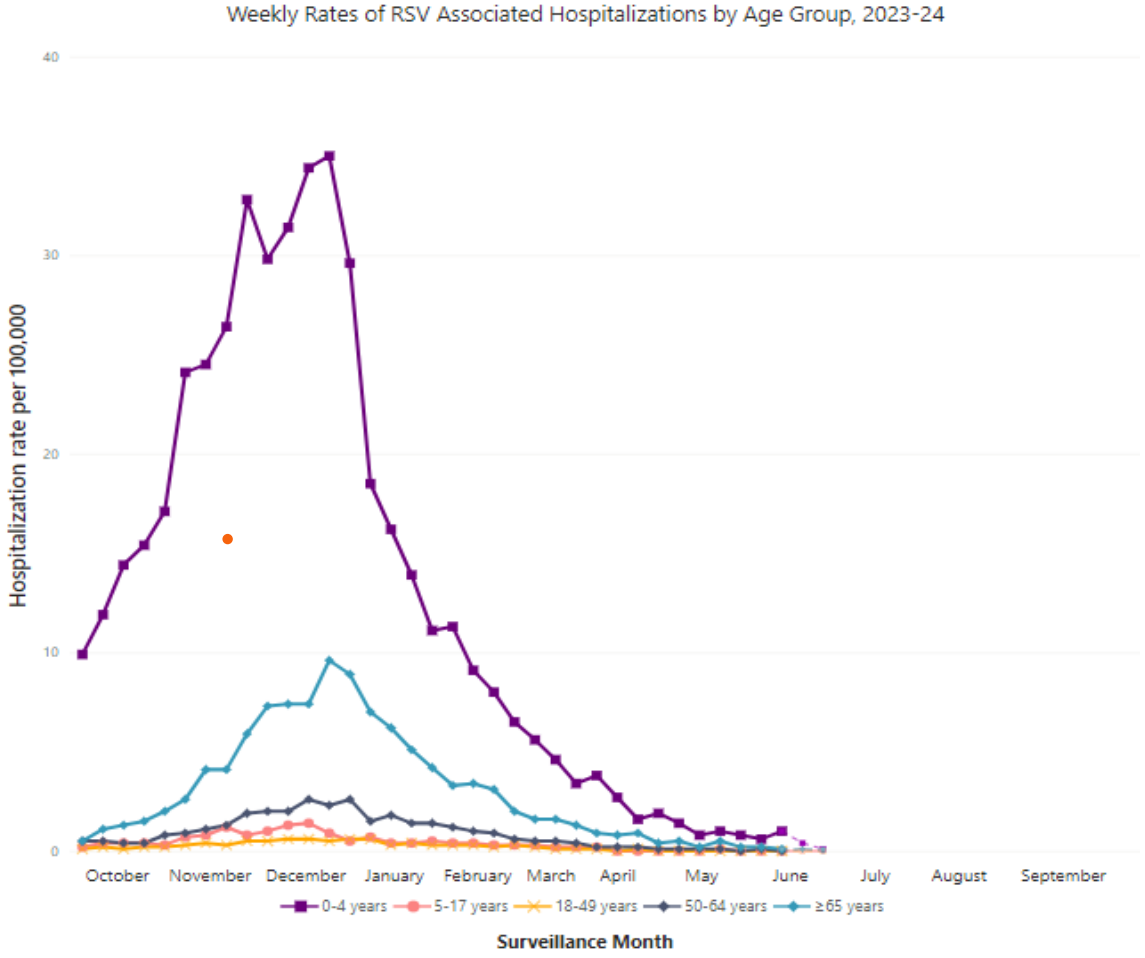
RSV- Net





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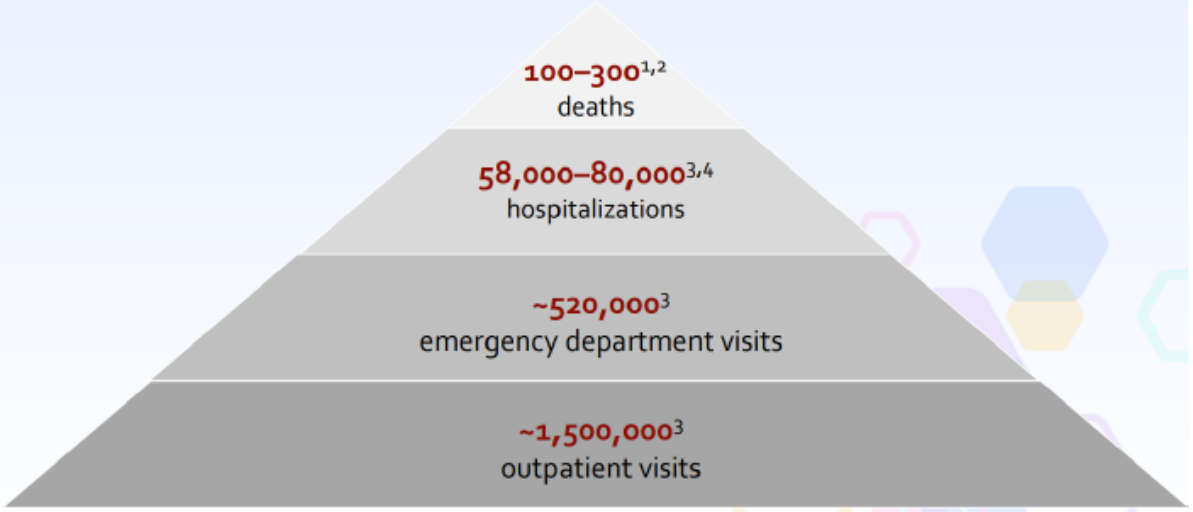
RSV in Children

- Common infection of childhood
  - 68% infected in 1st year of life
  - Nearly all (97%) infected by age 2
- Common cause of lower respiratory tract infection

Image: Goncalves et al. Critical Care Research and Practice 2012

Each year in U.S. children aged less than 5 years, RSV is associated with…



1Suh et al. JID 2022; 2Glezen et al, Arch Dis Child, 1986; 3Hall et al, Pediatrics, 2013; 4Langley & Anderson, PIDJ, 2011; 5CDC NVSN data

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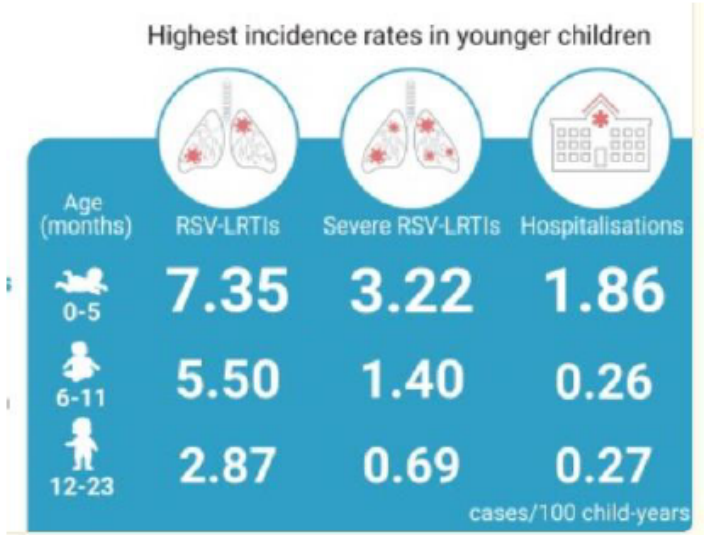
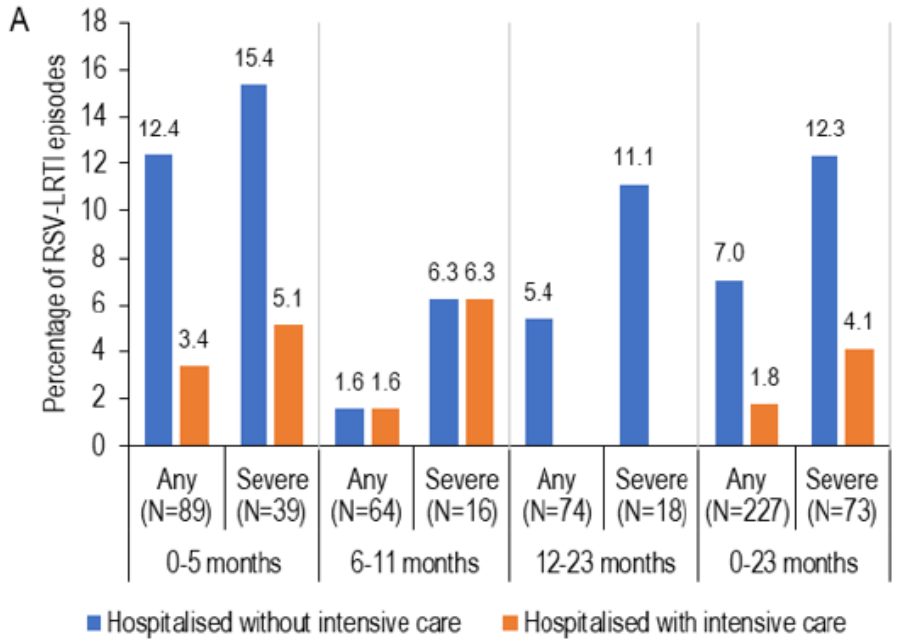
RSV Hospitalizations

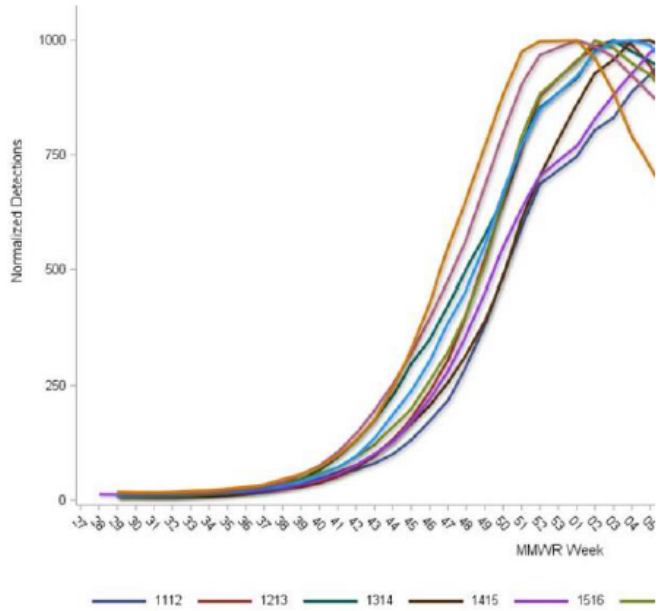
- Leading cause of hospitalization in U.S. infants
  - 2-3% of all infants hospitalized with RSV
- Preterm infants (<30wk) hospitalized 3X more often than term infants
- Highest RSV hospitalization rates occur in first months of life
- Risk decreases with increasing age in early childhood
- 79% of children <2y hospitalized with RSV had no underlying medical conditions

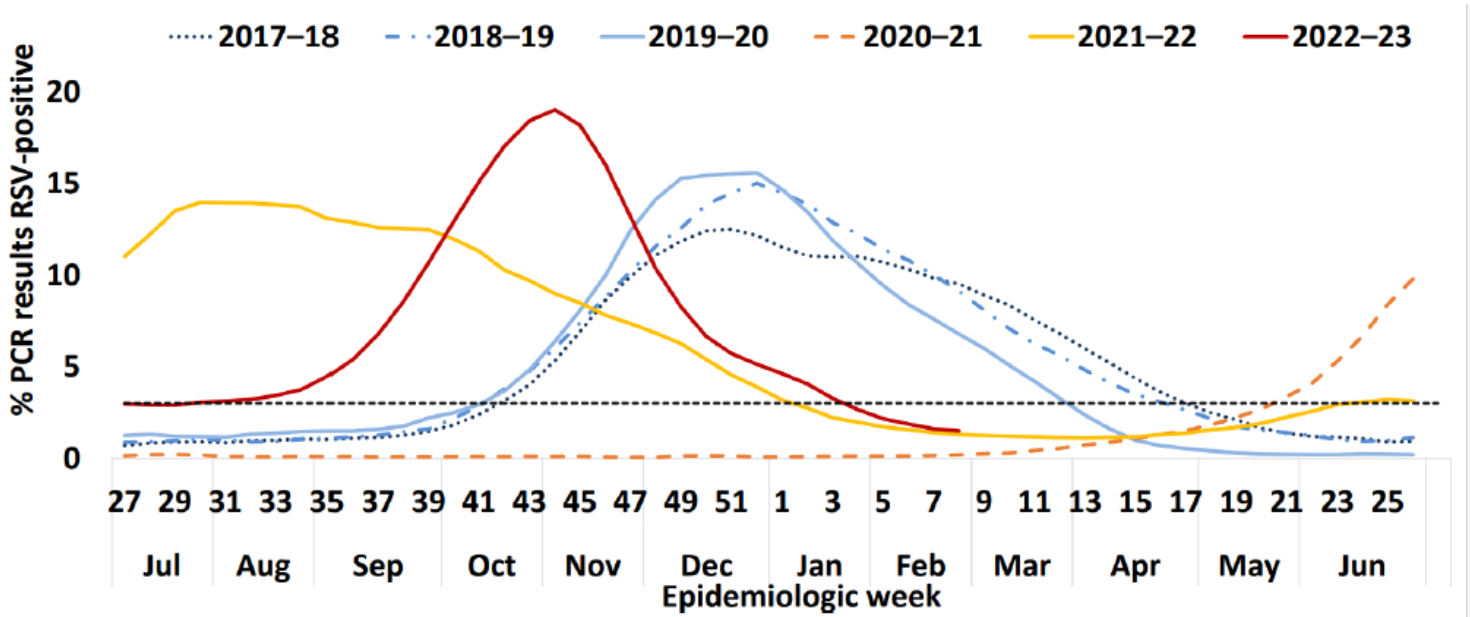




Long, SS. ACIP meeting 9/22/23
Langley JM, *J Infect Dis* 2022;226(3)

RSV Seaonality





Pre-COVID: Predicable seasonal peaks in US Dec-Feb

Post-COVID: intraseasonal wave peaking Aug 2021; severe early season in 2022

McMorrow M, ACIP Meeting, 6/23/22
Jones J, ACIP Meeting 8/3/23

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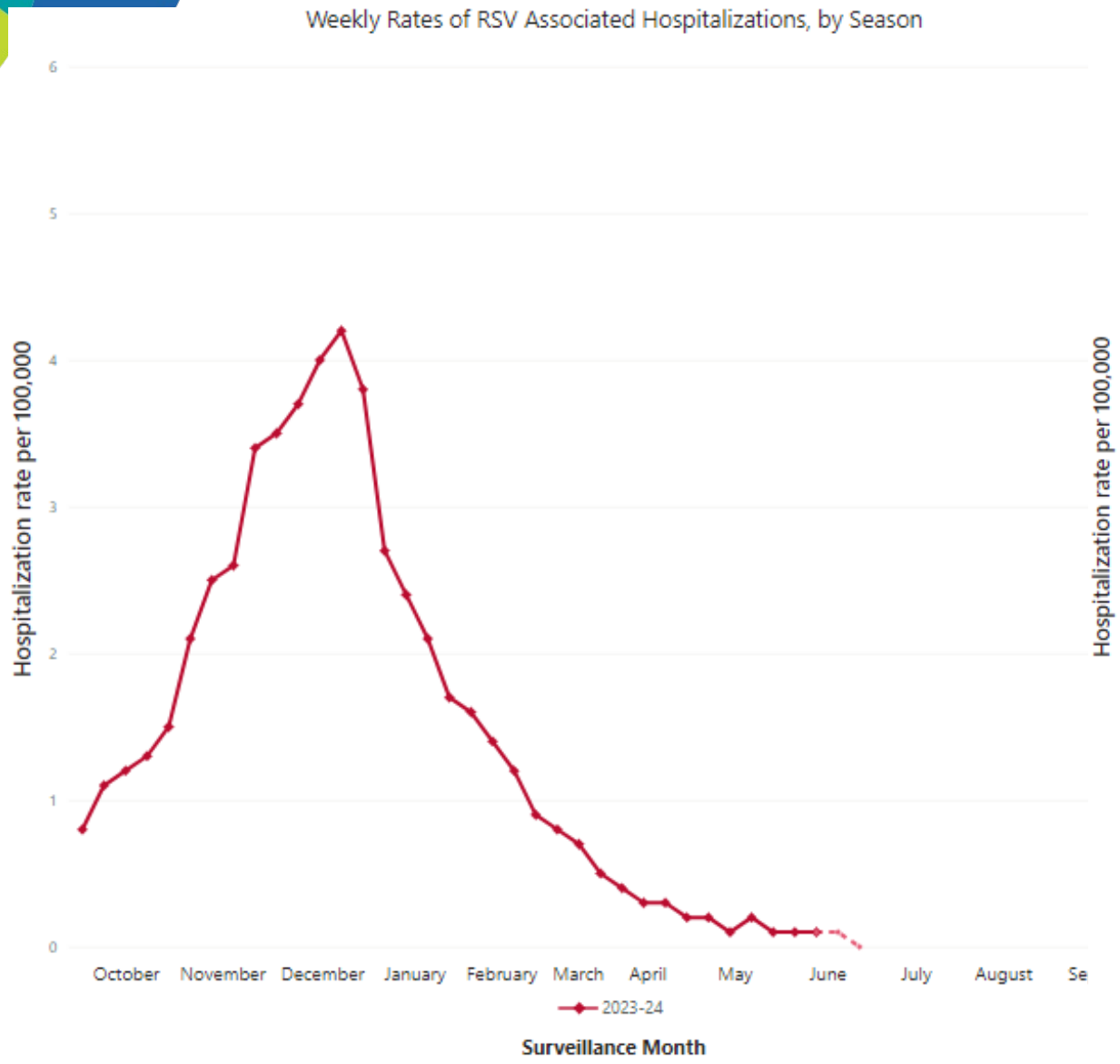
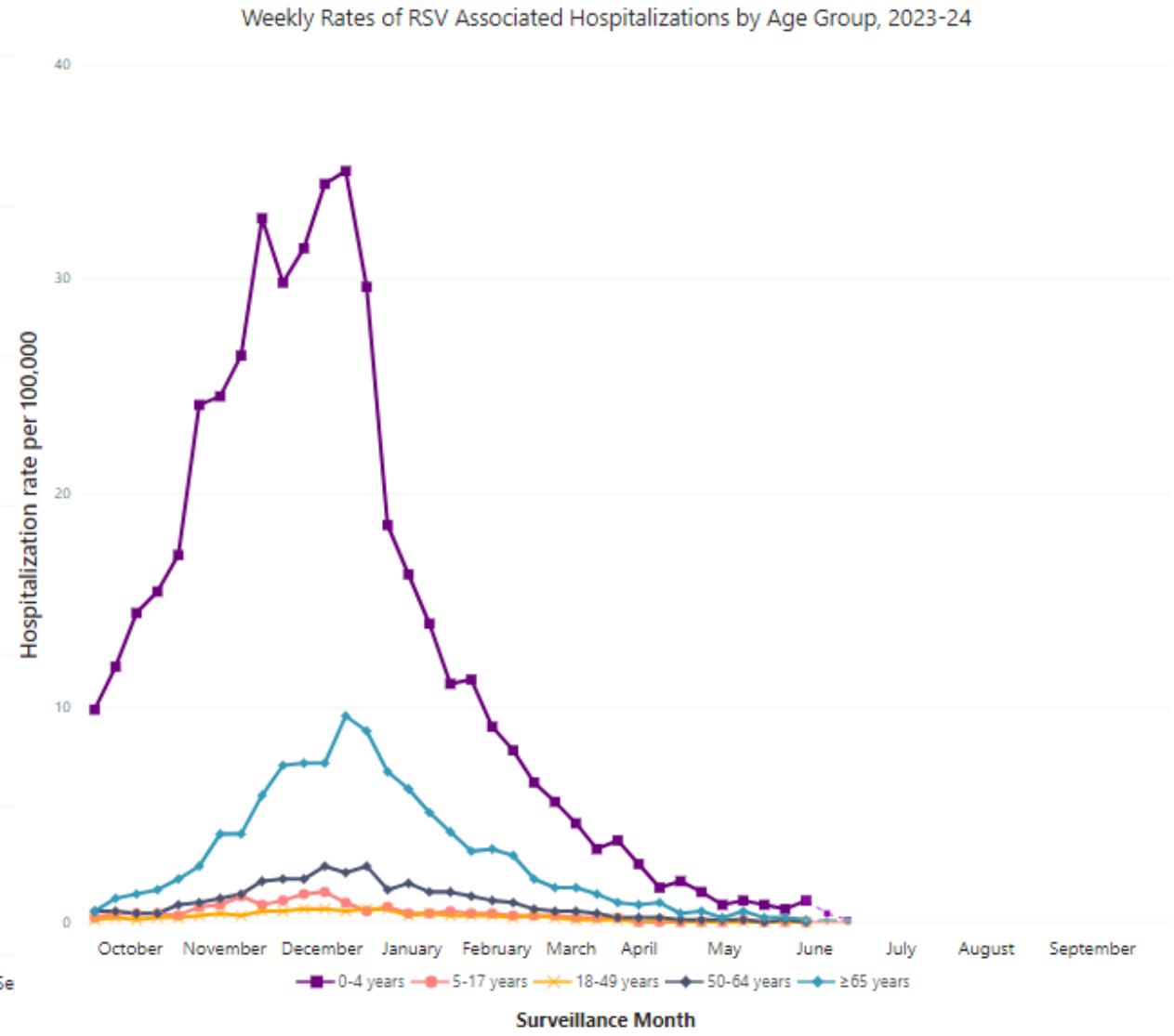
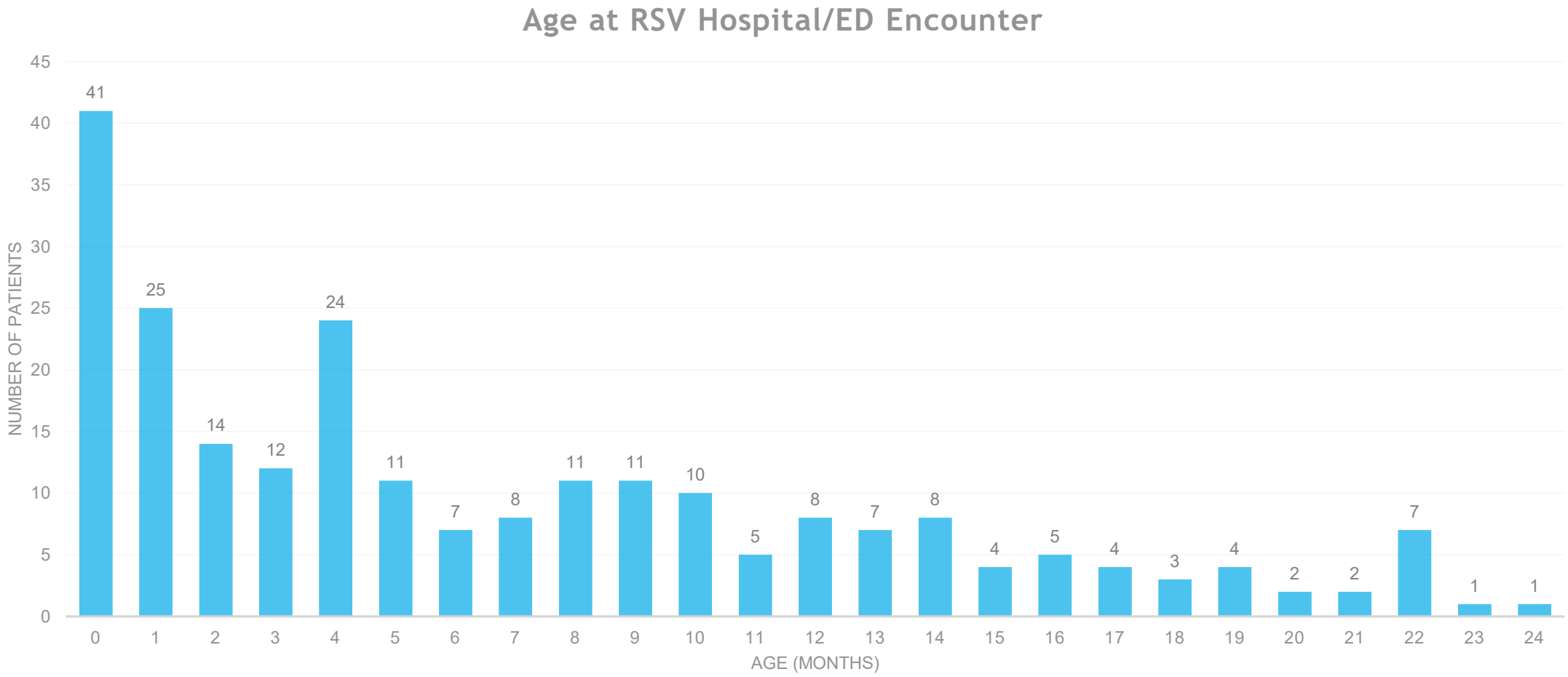
2023-241 RSV Season





Christiana Data 2023 Hospital



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New RSV Prevention Methods for Infants

Vaccination

- RSV vaccine (Pfizer only) given to mother during weeks 32-36 of gestation
- Four vaccines now recommended specifically for pregnant persons for respiratory illnesses:
  - COVID-19 (protects mom & baby)
  - Influenza (protects mom & baby)
  - Tdap (protects baby)
  - RSV (protects baby)

Immunization

- Monoclonal antibody (nirsevimab) given to all infants at birth or entering their first RSV season
  - High risk infants may receive 2nd dose entering their 2nd RSV season
- Essentially replaces palivizumab
  - Given monthly to high-risk infants only during RSV season
  - ~5% of U.S. infants eligible, ~2% received ≥1 doses

Both provide passive immunity – transfer of preformed antibodies produced externally – providing temporary protection to the recipient that wanes over time.

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Maternal RSV Vaccine Recommendation (Sept 2023)

- FDA approved for **32-36 weeks gestation**
- ACIP/CDC recommended **seasonal** dosing
  - Sept – Jan in most of continental US (typical RSV seasonality)
  - Flexibility in areas with atypical seasonality (Alaska, tropical climates)
- May be given simultaneously with other vaccines
  - Flu, COVID-19 (any trimester)
  - Tdap recommended for earlier gestational age (27-36, preferably before 32 wk)

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Maternal RSV Vaccine: Efficacy

Outcome	Trial dosing interval (24–36 weeks gestation)	Approved dosing interval (32–36 weeks gestation)
	Manufacturer calculated vaccine efficacy (CI)[1]	Manufacturer calculated vaccine efficacy (95% CI)[2]
Benefits		
Medically attended RSV-associated lower respiratory tract infection in infants (0–180 days)	51.3% (97.58% CI: 29.4, 66.8)	57.3% (95% CI: 29.8, 74.7)
Hospitalization for RSV-associated lower respiratory tract infection in infants (0–180 days)	56.8% (99.17% CI: 10.1, 80.7)	48.2% (95% CI: -22.9, 79.6)
ICU admission from RSV hospitalization in infants (0–180 days)	42.9% (95% CI: -124.8, 87.7)	1 event in the vaccine group 2 events in the placebo group
Mechanical ventilation from RSV hospitalization in infants (0–180 days)	100% (95% CI: -9.1, 100)	0 events in the vaccine group 2 events in the placebo group
All-cause medically attended lower respiratory tract infection in infants (0–180 days)	2.5% (99.17%: -17.9, 19.4)	7.3% (95% CI: -15.7, 25.7)
All-cause hospitalization for lower respiratory tract infection in infants (0–180 days)	28.9% (95% CI: -2.0, 50.8)	34.7% (95% CI: -18.8, 64.9)

VE vs. Severe RSV

- Required at least 1 of the following signs/ symptoms:
  - Fast breathing (respiratory rate ≥70 [<2 months of age] or ≥60 [≥2 to 12 months of age] breaths per minute
  - SpO2 measured in room air <93%
  - High-flow nasal cannula or mechanical ventilation
  - ICU admission for >4 hours
  - Unresponsive/unconscious

Time period after birth	Trial dosing interval (24–36 weeks gestation) Vaccine efficacy[1] (99.5% or 97.58% CI)	Approved dosing interval (32–36 weeks gestation) Vaccine efficacy[2] (95% CI)
0–90 days after birth	81.8% (40.6, 96.3)	91.1% (38.8, 99.8)
0–180 days after birth	69.4% (44.3, 84.1)	76.5% (41.3, 92.1)

Fleming-Dutra K, ACIP Meeting 9/22/23

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Maternal RSV Vaccine: Safety

Outcome	Trial dosing interval[1] (24–36 weeks)	Approved dosing interval[1] (32–36 weeks)
	Relative Risk[2] (95% CI)	Relative Risk[2] (95% CI)
Harms		
Serious adverse events in pregnant people	1.06 (0.95, 1.17)	1.02 (0.87, 1.20)
Reactogenicity (grade 3+) in pregnant people	0.97 (0.72, 1.31)	0.98 (0.62, 1.54)
Serious adverse events in infants	1.01 (0.91, 1.11)	1.04 (0.90, 1.20)
Preterm birth (<37 weeks gestation)	1.20 (0.99, 1.46)	1.15 (0.82, 1.61)

- Imbalance in preterm birth seen in similar GSK maternal vaccine (6.81% vs. 4.95%, RR 1.38) → trial halted
- Seen in low/middle-income countries but not high-income countries
- No cases of Guillain-Barré syndrome (GBS) in pregnant women (all cases ≥60y)

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RSV in preterm birth

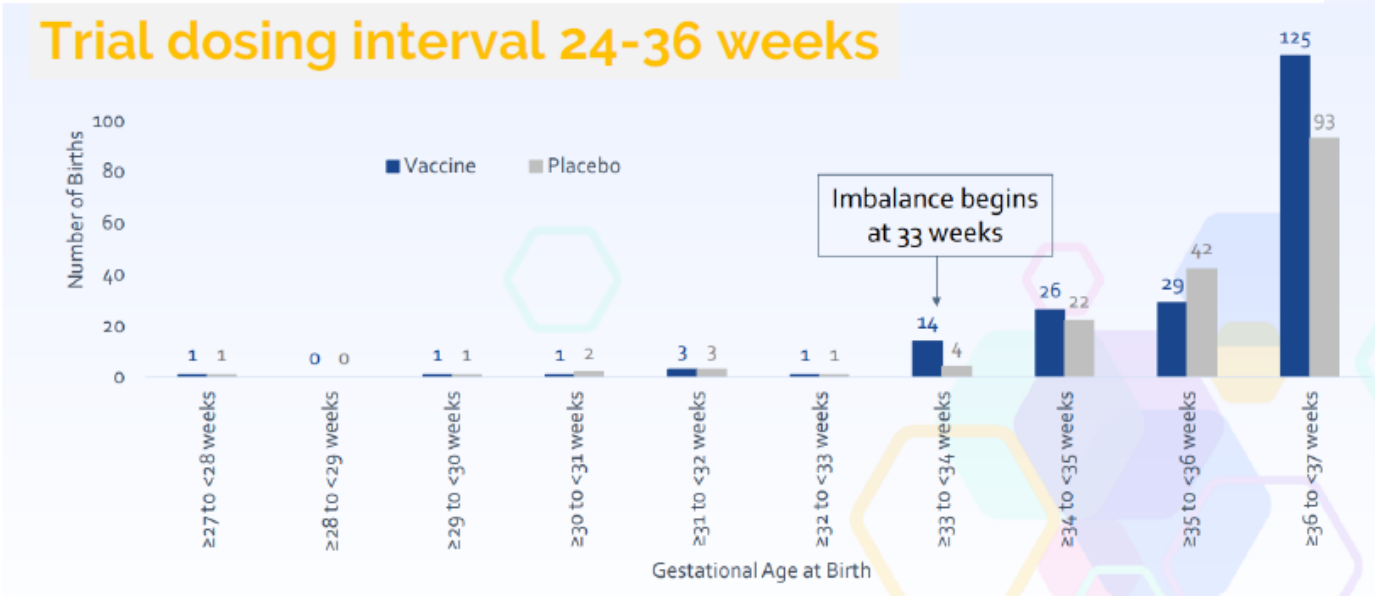
Preterm birth[a] risk among pregnant persons receiving RSV vaccine and unvaccinated matches, 30–36 weeks GA

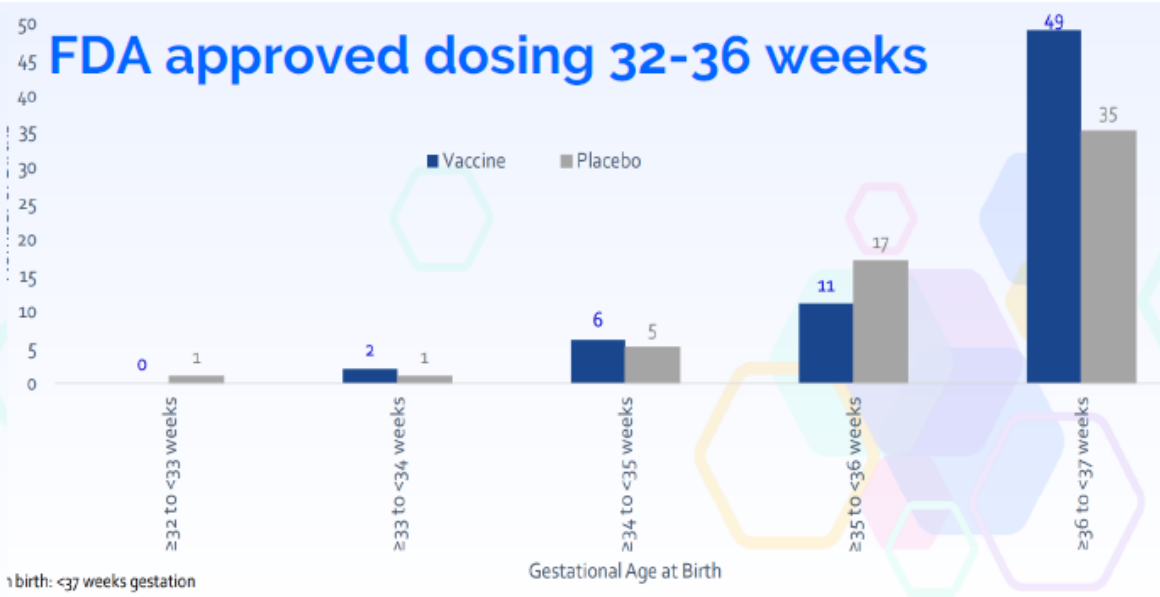
	Matched pairs, N	RSV vaccinated		Unvaccinated match		Risk Ratio (95% CI)
		N events*	Preterm birth %	N events*	Preterm birth %	
Overall[b]	14,099	571	4.0	637	4.5	0.90 (0.80–1.00)
32–36 weeks	13,965	563	4.0	628	4.5	0.90 (0.80–1.00)

GA = gestational age
[a]Preterm birth = birth <37 weeks gestational age
[b]N RSV vaccines administered <32 weeks = 134 (0.95%)
*Events only included through date of censoring when unvaccinated pair crosses over to vaccinated

Pfizer RSVpreF: Preterm Births

	Trial dosing interval (24–36 weeks gestation)[1]				Approved dosing interval (32–36 weeks gestation)[1,2]			
	RSVpreF vaccine group N=3,568		Placebo group N=3,558		RSVpreF vaccine group N=1,628		Placebo group N=1,604	
	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)
Preterm birth (<37 weeks gestation)	202	**5.7%** (4.9%, 6.5%)	169	**4.7%** (4.1%, 5.5%)	68	**4.2%** (3.3%, 5.3%)	59	**3.7%** (2.8%, 4.7%)





SGA Risk

SGA[a] at birth risk in infants born to RSV vaccinated pregnant person or unvaccinated pregnant matches, 30–36 weeks GA[b]

	Matched pairs, N	RSV vaccinated		Unvaccinated match		Risk Ratio (95% CI)
		N events*	SGA at birth %	N events*	SGA at birth %	
Overall	11,920	800	6.7	781	6.6	1.02 (0.93–1.13)
32–36 weeks	11,819	799	6.8	774	6.5	1.03 (0.94–1.14)

[a]SGA at birth = "Small for Gestational Age"; birthweight <10th percentile for gestational age compared with a U.S. reference population[1]

[b]GA = gestational age

*Events only included through date of censoring when unvaccinated pair crosses over to vaccinated

Note: 11,920 matched pairs with complete infant weight data (85%)

HealthPartners Institute

[1]Talge NM, Mudd LM, Sikorskii A, Basso O. United States birth weight reference corrected for implausible gestational age estimates. Pediatrics 2014;133:84453. PMID:24777216

Pregnancy-related Serious Adverse Events

	RSVpreF Vaccine N= 3,682		Placebo N= 3,675	
Serious Adverse Reaction	**n (%)**	**95% CI**	**n (%)**	**95% CI**
All Maternal Serious Adverse Events (SAEs)	**598 (16.2)**	**(15.1, 17.5)**	**558 (15.2)**	**(14.0, 16.4)**
Pre-eclampsia	68 (1.8)	(1.4, 2.3)	53 (1.4)	(1.1, 1.9)
Gestational hypertension	41 (1.1)	(0.8, 1.5)	38 (1.0)	(0.7, 1.4)
Premature rupture of membranes	15 (0.4)	(0.2, 0.7)	16 (0.4)	(0.2, 0.7)
Preterm premature rupture of membranes	15 (0.4)	(0.2, 0.7)	10 (0.3)	(0.1, 0.5)
Hypertension	13 (0.4)	(0.2, 0.6)	6 (0.2)	(0.1, 0.4)
Maternal death[3]	1 (<0.1)	(0.0, 0.2)	0	(0.0, 0.1)
Fetal death[4]	10 (0.3)	(0.1, 0.5)	8 (0.2)	(0.1, 0.4)

1 Table 3 ABRYSVO package insert Package Insert - ABRYSVO (STN 125768) (fda.gov)

2 Includes all SAEs from vaccination to 6 months post-delivery (up to approximately 10 months, depending on the gestational age at the time of vaccination). In the phase 3 RCT, eclampsia occurred in 5 participants (3 in the RSVpreF group and 2 in the placebo group) and HELLP syndrome occurred in 5 participants (2 in the RSVpreF group and 3 in the placebo group).

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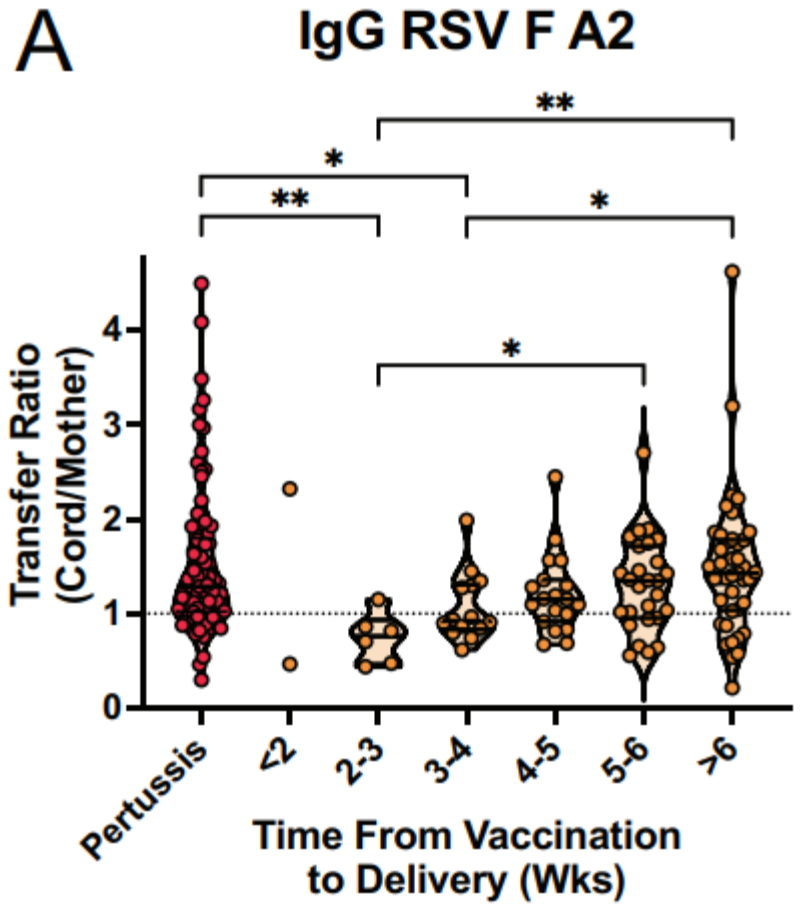
Fleming-Dutra K, ACIP meeting, 9/22/23

Does Timing of Vaccination Matter?

- Looked at timing of IGG in cord blood from immunization to delivery
- N=122



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Nirsevimab Recommendation
8/3/23

- Timing:
  - In 1st week of life for infants born shortly before and during RSV season
    - Inpatient or outpatient
    - If prolonged birth hospitalizations: before or promptly after discharge
  - Shortly before the start of RSV season for infants <8 months
  - *Shortly before start of RSV season for children aged 8–19 months at increased risk of severe RSV disease*
- RSV season:
  - October through end of March (most of continental US)
  - Providers may adjust based on local epidemiology
- Can be co-administered with other routine vaccinations

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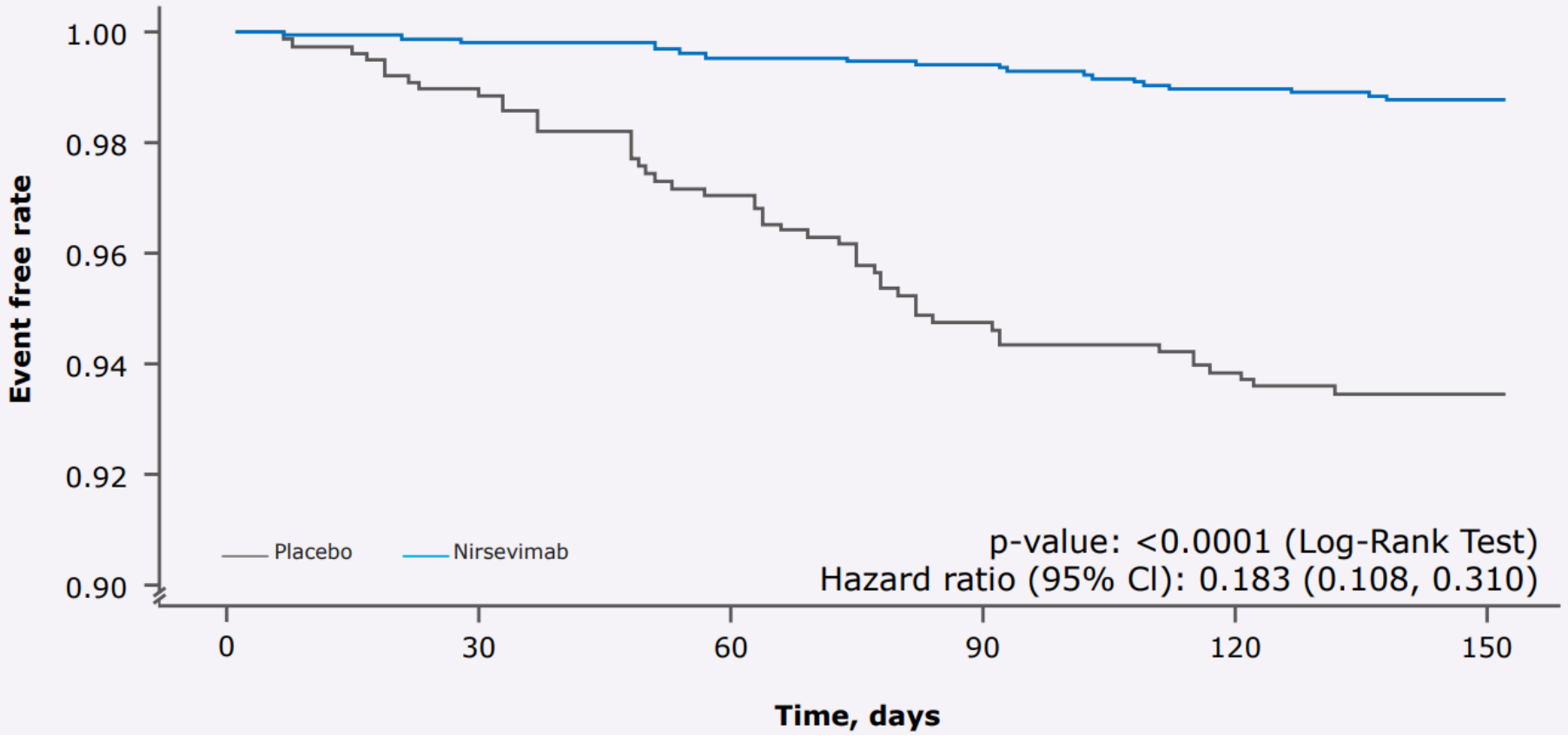
Nirsevimab-Efficacy

Time to first RSV-confirmed MA LRTI



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Nirsevimab: Safety

MedDRA SOC	MedDRA Preferred Term	Frequency
Skin and subcutaneous tissue disorders	Rash[1]	Uncommon
General disorders and administration site conditions	Injection site reaction[2]	Uncommon
	Pyrexia[3]	Uncommon

[1] Rash was defined by the following grouped preferred terms: rash, rash maculo-papular, rash macular, occurring within 14 days post dose.
[2] Injection site reaction was defined by the following grouped preferred terms: injection site reaction, injection site pain, injection site induration, injection site oedema, injection site swelling, occurring within 7 days post dose.
[3] Pyrexia occurring within 7 days post dose.

No serious adverse events, deaths
No anaphylaxis or serious allergic reactions attributable to nirsevimab

No vaccine-mediated enhanced disease (VMAD) or shift in RSV severity to 2nd RSV season

Definition, n (%)	RSV Season 1 (2019-2020): To Day 151		RSV Season 2 (2020-2021): Days 361 – 511	
	Placebo (n=496)	Nirsevimab (n=994)	Placebo (n=482)	Nirsevimab (n=964)
All MA LRTI (any cause)*	77 (15.5)	92 (9.3)	22 (4.6)	37 (3.8)
All MA respiratory illness with hospitalization (any cause)*	16 (3.2)	24 (2.4)	3 (0.6)	4 (0.4)

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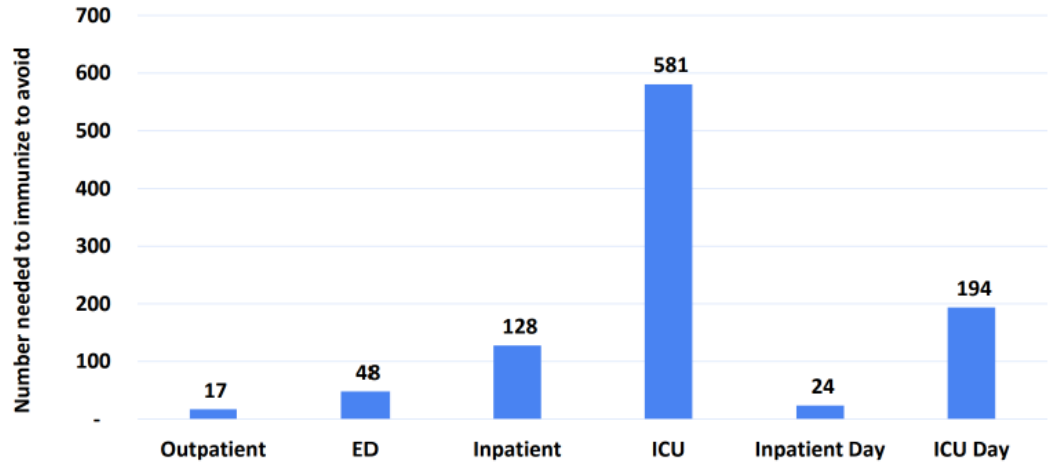
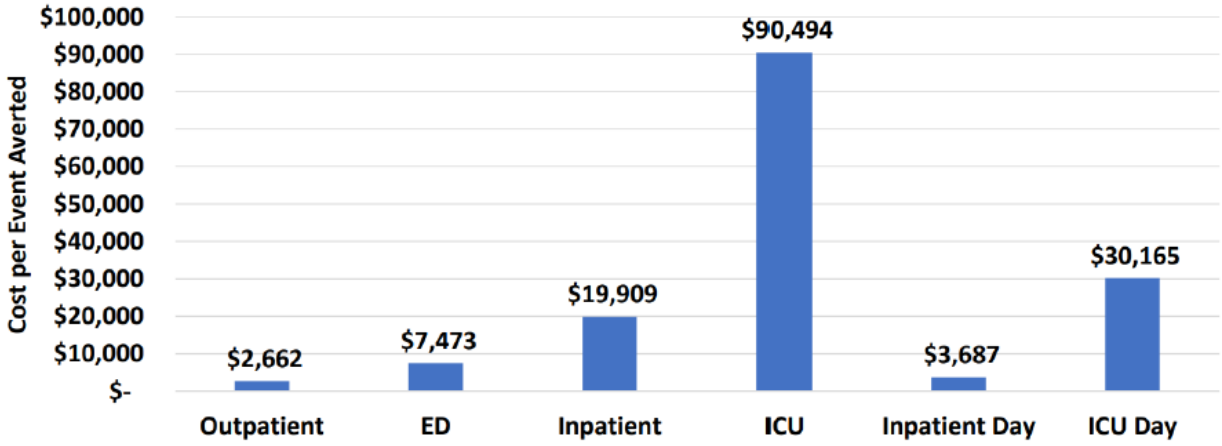
Nirsevimab-NNT

Cost:

- $495 list price
- $395 VFC price
- Average $445 (50% VFC)
- Includes cost savings by not using palivizumab (>$2000/50 mL)

- CE (base case):
  - $102,811 per QALY





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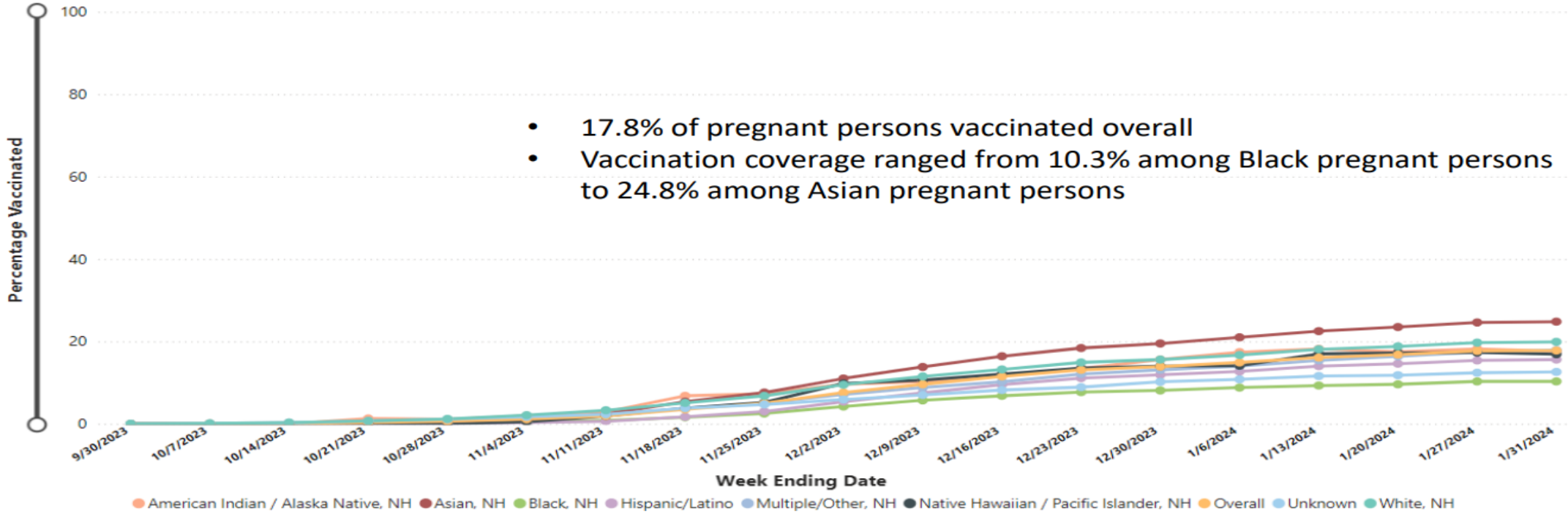
RSV Vaccine uptake 2023-24 Season

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

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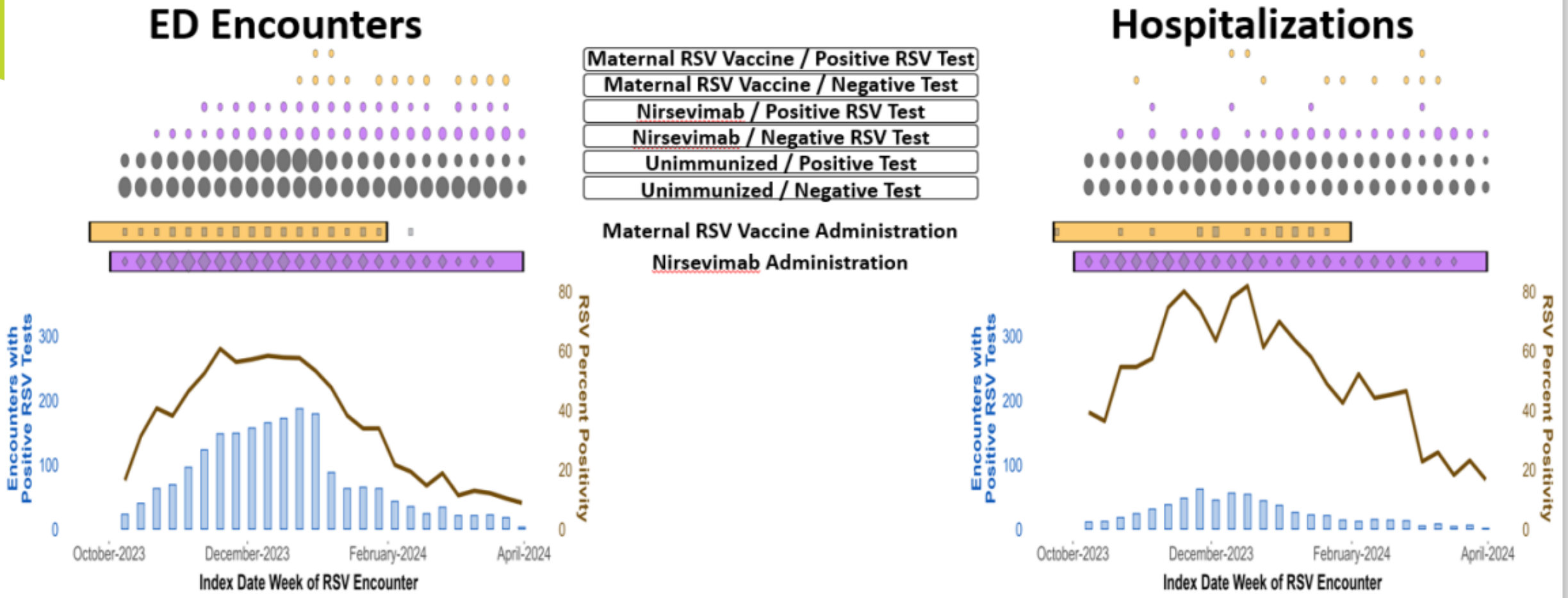
ED Encounters and Hospitalizations for RSV-like illness* among infants in their first RSV season, by immunization and RSV positivity status – VISION, October 2023 – March 2024



Payne A, ACIP Meeting, 6/28/24

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Nirsevimab or Vaccine 2023-24 Season

Proportion of infants protected from RSV by receipt of nirsevimab or maternal RSV vaccination

- **51.2% of infants are estimated to be protected from RSV by either receipt of nirsevimab or maternal RSV vaccination.**
- Infants eligible for nirsevimab: 3,900,000
  - Those 0–7 months old during October 2023–March 2024
  - Born March 2023–March 2024
  - Assume 300,000 babies born each month
  - 43.0% received nirsevimab (from February NIS-ACM)
- Infants eligible for protection by maternal vaccination (a subset of infants eligible for nirsevimab): 1,800,000
  - Born October 2023–March 2024
  - Born to mothers 32-36 weeks' gestation and eligible for RSV vaccination September 2023–January 2024
  - 17.8% of mothers received RSV vaccination (from VSD data through January 2024)
- Estimated number of infants who received nirsevimab = .430*3,900,000 = 1,677,000
- Estimated number of infants protect by maternal RSV vaccination = .178*1,800,000 = 320,400
- **Percent protected by either = 1,677,000 + 320,400 / 3,900,000 = 51.2%**

Stockley S, ACIP meeting, 6/28/24

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Challenges of the 2023-24 Season

- Multiple products introduced immediately prior to RSV season □significant confusion
- •Vaccine access issues (pharmacy denials, lack of supply at OB offices, insurance coverage)
- •Significant shortages of nirsevimab□Made counseling re: vaccine more challenging
- Differential availability for VFC vs. private insurance
- •Errors reported (nationally):Mothers receiving GSK vaccine, not Pfizer
- Infants receiving vaccine, not monoclonal Ab
- Wrong dose of monoclonal Ab administered

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Current Implementation

- Grand Rounds & Multiple reminders, FAQ sheets in the practices
- RSV vaccination available at All employed OB practices and MFM
- Not being offered by private providers
- Nirsevimab- Made available to all NICU graduates
- Not available to all non-NICU infants during birth hospitalizations
- Available at all employed pediatric practices

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Questions/Discussion