ILPQC & IDPH Webinar Series: The 4 Vaccines Recommended During Pregnancy

October 2, 2024

12-1:00pm

ILPQC
Illinois Perinatal Quality Collaborative

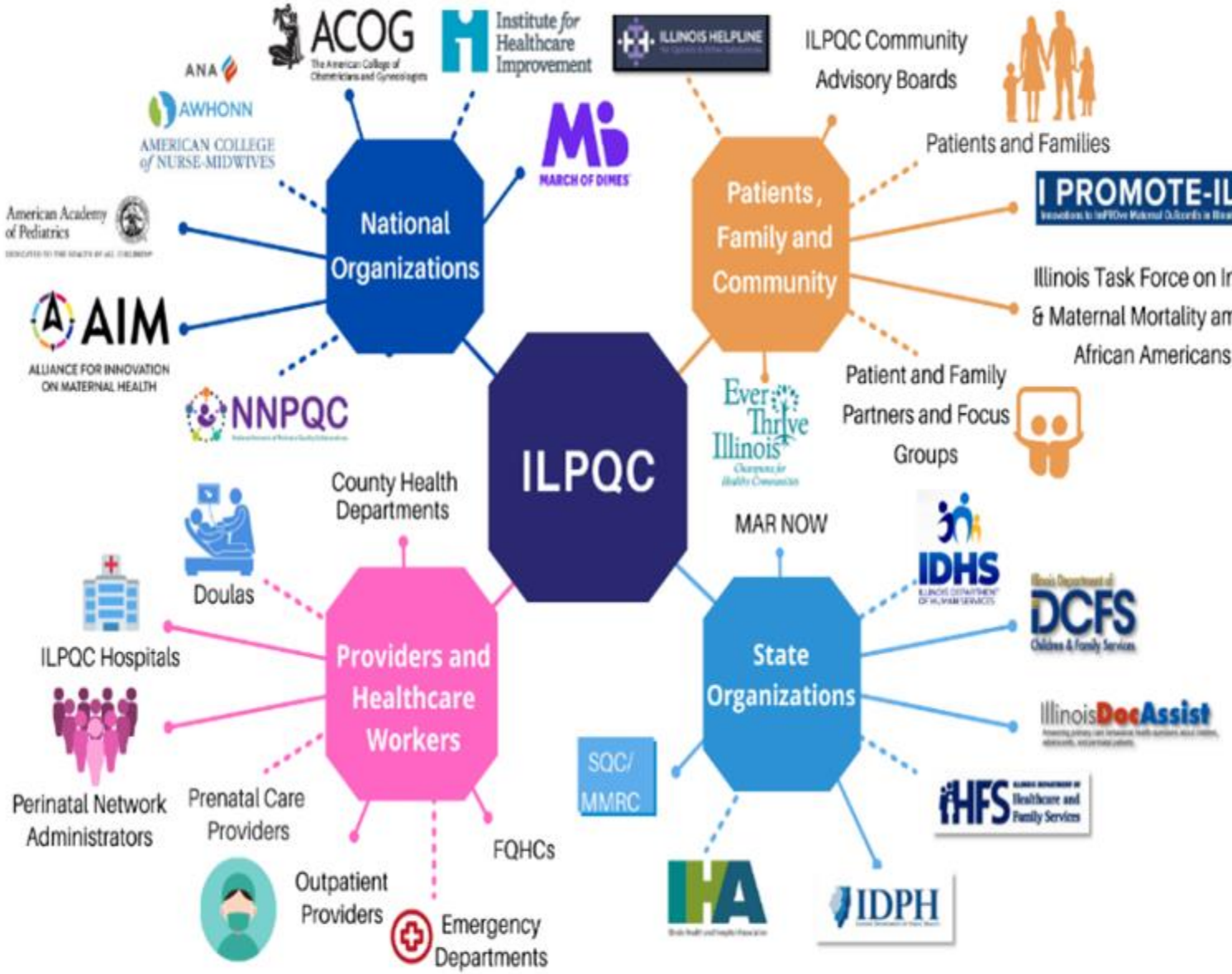
Call Overview

- Overview: Ann Borders, MD, MSc, MPH, Illinois Perinatal Quality Collaborative, Endeavor Health Evanston Hospital
- 4 Vaccines Recommended During Pregnancy: Kiki Ogu, MD, Northwestern University
- Pediatric RSV Vaccine, Vaccine Access and Vaccine Counseling: Leena Mithal, MD, MSCI, Lurie's Children's Hospital
- VFC Program: Leslie Caldarelli, MD, Illinois Perinatal Quality Collaborative, Lurie's Children's Hospital
- Resources & Next Steps: Ann Borders

Illinois Perinatal Quality Collaborative

Statewide network of hospital teams, perinatal clinicians, patients, community partners, and public health leaders.

Committed to equitably improving outcomes and reducing disparities for birthing people and newborns in Illinois.



Overview of 4 vaccines recommended in pregnancy: what providers need to know

Kiki Ogu, MD

Northwestern Memorial Hospital

IL PQC
Illinois Perinatal Quality Collaborative

Overview of 4 vaccines recommended in pregnancy: what providers need to know

Kiki Ogu MD
Maternal fetal medicine fellow
Northwestern University

No financial disclosures

Objective

To review the physiology on maternal immunization

To discuss the current recommendations of maternal vaccination

To provide resources to support vaccination uptake

Outline

01 . Maternal immunization

02 . Influenza

03 . Tdap

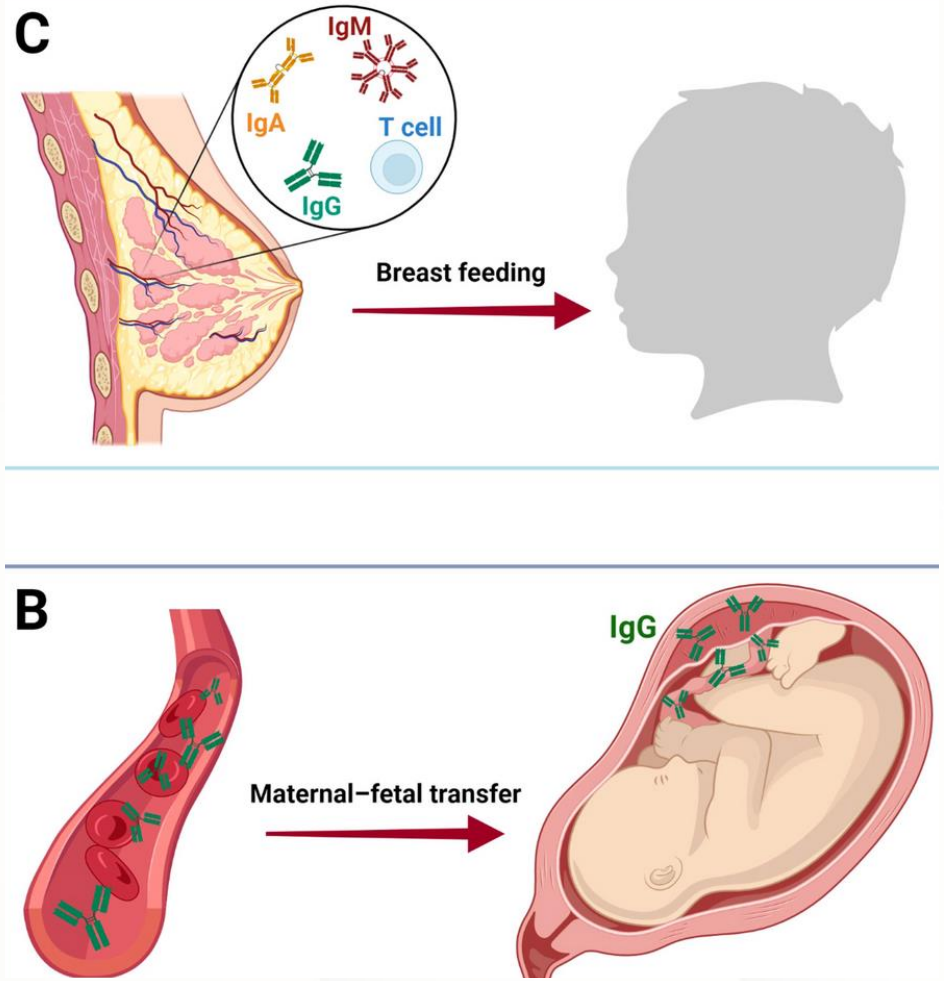
04 . COVID-19

05 . RSV

06 . Patient counseling

Pregnancy and the Immune System

- Pregnancy poses increased risk of infectious morbidity
- Newborn period allows for a gap in immunity
- **Maternal immunization provides dual protection for pregnant person and newborn**



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Maternal Immunization

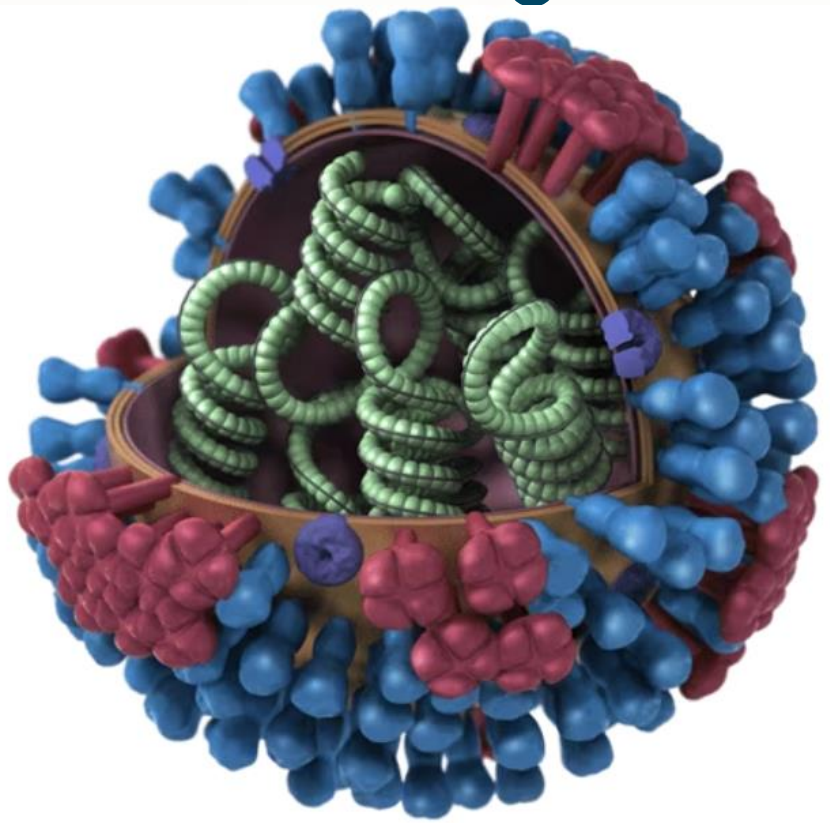
Influenza

Tdap

COVID-19

RSV

Seasonal Influenza Virus



Virology
- Influenza type A and B
- Single stranded RNA virus
- Transmission via respiratory droplets
- Seasonal from September through April

Disease burden
- Seasonal influenza infects ~ 1 billion people annually
- 3-5 million cases of severe illness
- 290,000 to 650,000 respiratory deaths annually
  - October-April 2024 24,000-67,000 deaths

Risk factors
- Chronic lung disease, asthma, diabetes, **pregnancy**, and heart disease

Influenza Vaccine

- Single dose of **inactivated vaccine** should be administered for all pregnant persons during flu season
- Pregnant people who find themselves in their third trimester in August, may receive the vaccine for neonatal protection*

Who should not receive the vaccine?

- Individuals with anaphylaxis
- Recommend monitoring post administration in setting of egg allergy
- Recommend consultation with MD with history of Guillain-Barre syndrome

Influenza in Pregnancy

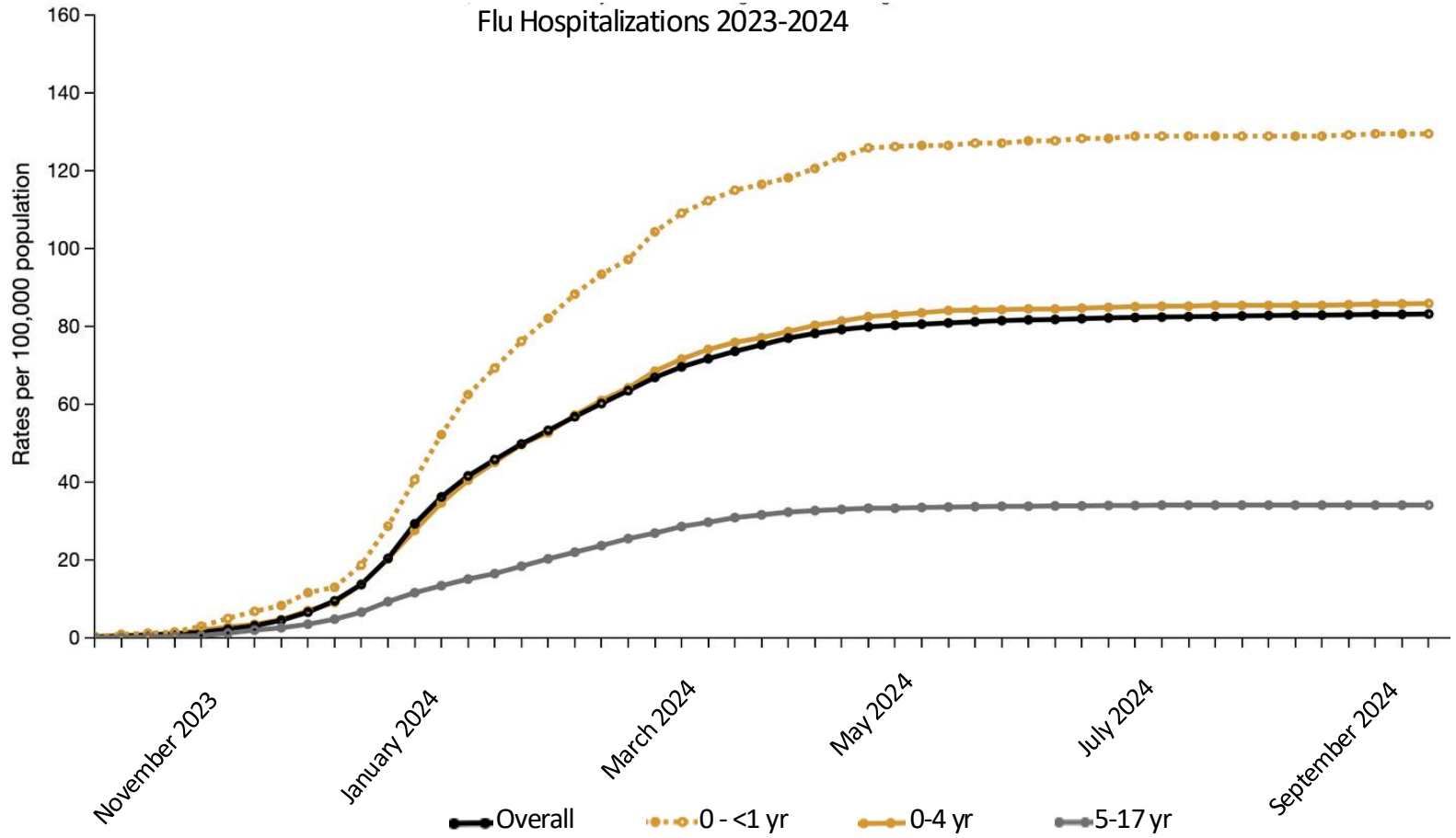
- Influenza in pregnancy is more likely to require hospitalization compared to infection in non-pregnant individual

Maternal benefit of vaccination

- A flu vaccine reduces a pregnant person's risk of being hospitalized with flu by an average of 40%
- CDC Vaccine Safety Data concluded no increase in miscarriage or stillbirth

Influenza in the Pediatric Population

Flu hospitalization rates are highest in children under 5 years



0- <1 years:
Rate= 129.5 per 100,000

0-4 years:
Rate= 85.9 per 100,000

5-17 years:
Rate= 34.1 per 100,000

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Influenza Vaccine Protection for Baby

Neonatal benefit

- Passive immunity reduced flu illness and flu related hospitalizations for the first several months after their birth

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ORIGINAL ARTICLE

Effectiveness of Maternal Influenza Immunization in Mothers and Infants

K. Zaman, M.B., B.S., Ph.D., Eliza Roy, M.B., B.S., D.C.H., Shams E. Arifeen, M.B., B.S., Dr.P.H., Mahbubur Rahman, M.B., B.S., Ph.D., Rubhana Raqib, Ph.D., Emily Wilson, M.H.S., Saad B. Omer, M.B., B.S., Ph.D., Nigar S. Shahid, M.B., B.S., M.P.H., Robert F. Breiman, M.D., and Mark C. Steinhoff, M.D.

- Vaccine efficacy maternal: 64.2% (95% CI 42-97%)
- Vaccine efficacy neonate: 62.8% (95% CI 2-85%)

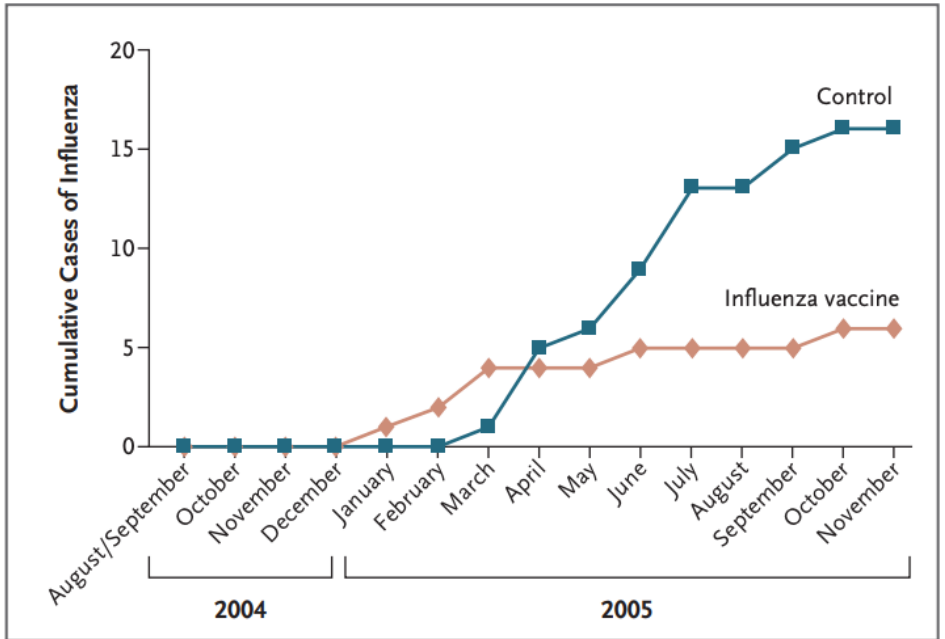

Figure 2. Cumulative Cases of Laboratory-Proven Influenza in Infants Whose Mothers Received Influenza Vaccine, as Compared with Control Subjects.

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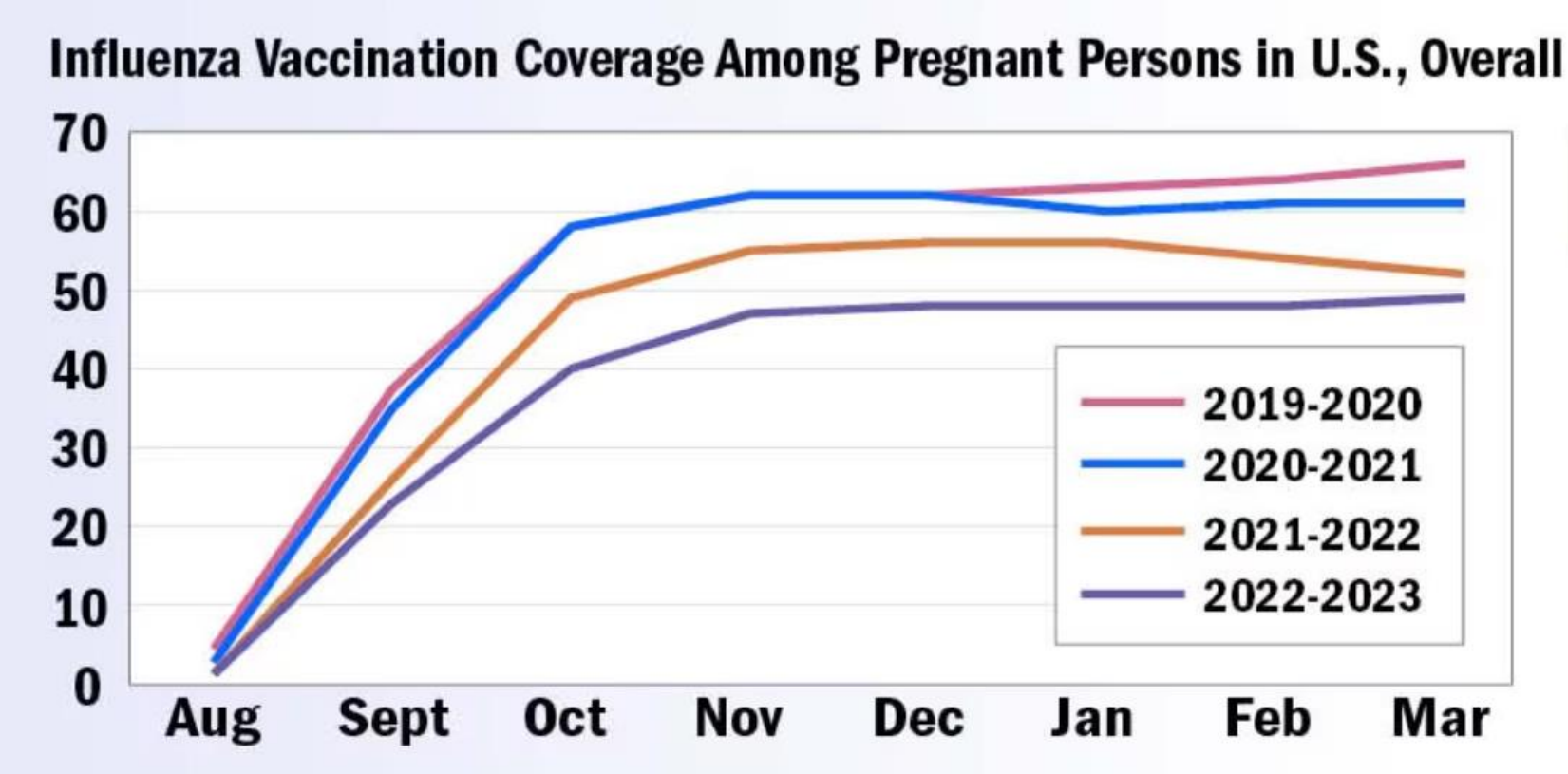
Vaccine Uptake

Despite numerous benefits for mom and baby, flu vaccine coverage remains poor



Current Recommendation

SMFM, ACOG, CDC/ACIP recommend all pregnant persons receive vaccination against seasonal influenza virus regardless of trimester

Flu vaccine reduces risk for mom during pregnancy and reduces risk for the baby during the first year

Pertussis (Whooping Cough)

Virology

- Bacterium Bordetella pertussis a gram-negative coccobacillus
- Transmission via airborne droplets

Disease burden

- Causes highly contagious respiratory tract infections called whooping cough
- Major cause of morbidity and mortality in infants

- Pertussis often affects 100% of non-immune household contacts
- **Largely remains a pediatric disease, with 38% of cases occurring in infants younger than 6 months**
- **Infant death rate is about 2%**

Risk factors

- Close contacts, unvaccinated, prematurity, infants

Tdap Vaccination

A single dose of Tdap should be administered during **every pregnancy,** preferably during the early part of **gestational weeks 27 through 36**

- **Administer** Tdap in the immediate **postpartum** period **if** the patient did not receive Tdap during their pregnancy and has not previously received a Tdap vaccination

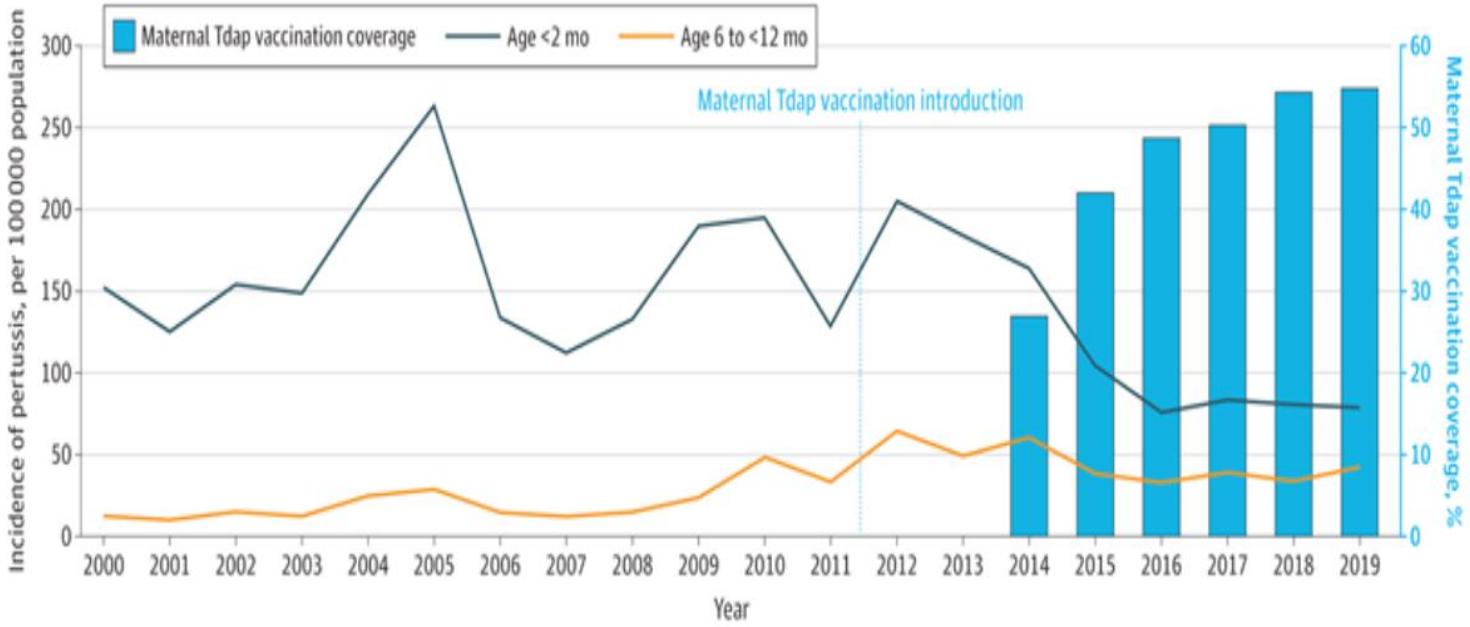
- If a patient did not receive Tdap during their pregnancy but **did receive a prior dose of Tdap**, then **do not** administer a dose postpartum.

- If incomplete or unknown tetanus vaccination, then administer Td at 0, 4weeks, 6 months and replace a single dose with Tdap between 27-36 weeks

Impact of Tdap Vaccination to protect newborns through 1 year

Uptake in vaccination associated with significant reduction in incidence of neonatal 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



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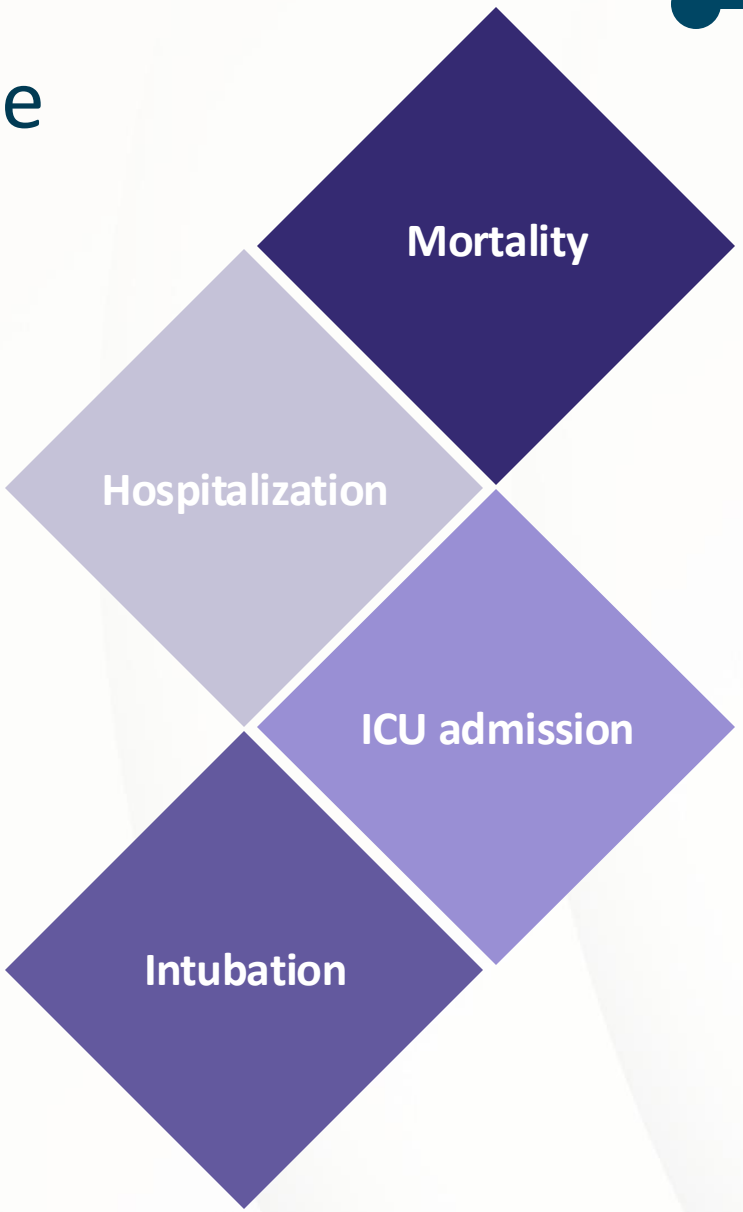
Impact of Tdap Vaccination to reduce risk for newborns

Tdap vaccination during the third trimester of pregnancy prevents 78% of pertussis cases in infants younger than 2 months of age.

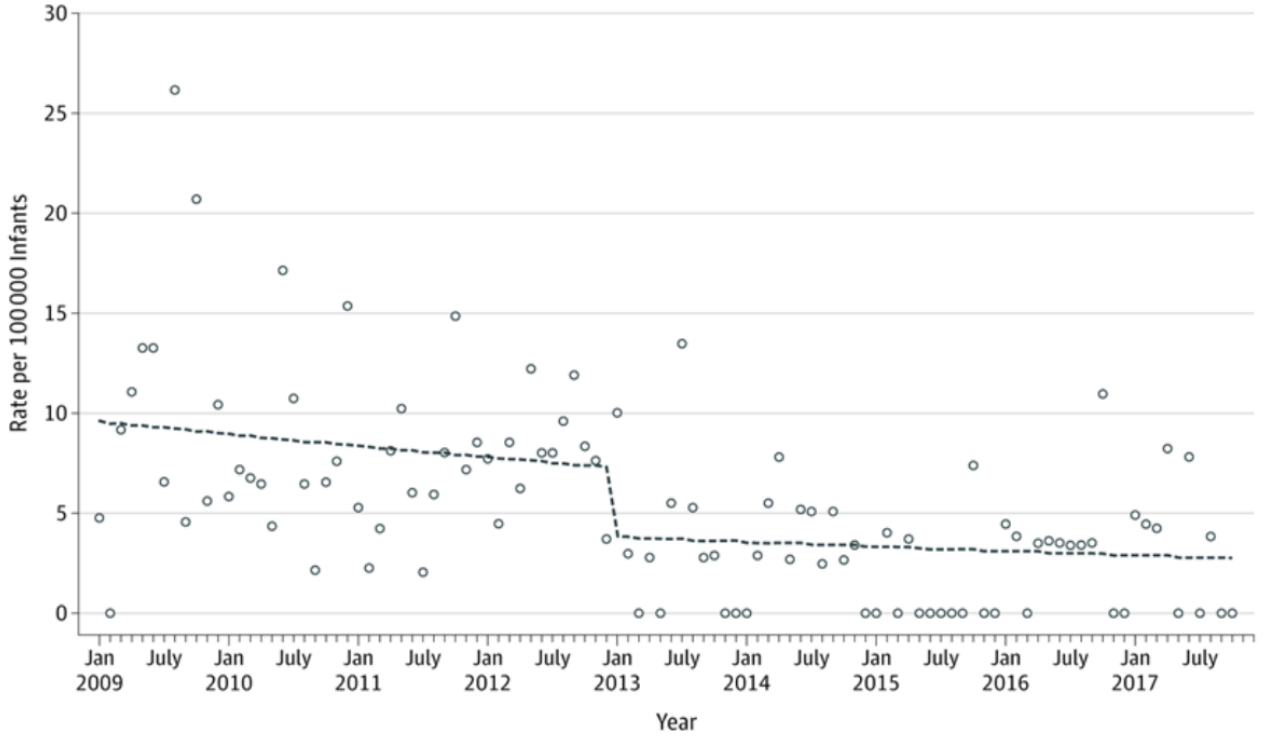
Additional benefits include reduction in:



Impact of Tdap Vaccination to protect newborns

Maternal immunization confers improved protection compared to cocoon

Figure. Monthly Infant Pertussis Hospitalizations Between Birth and 2 Months of Age, 2009-2017



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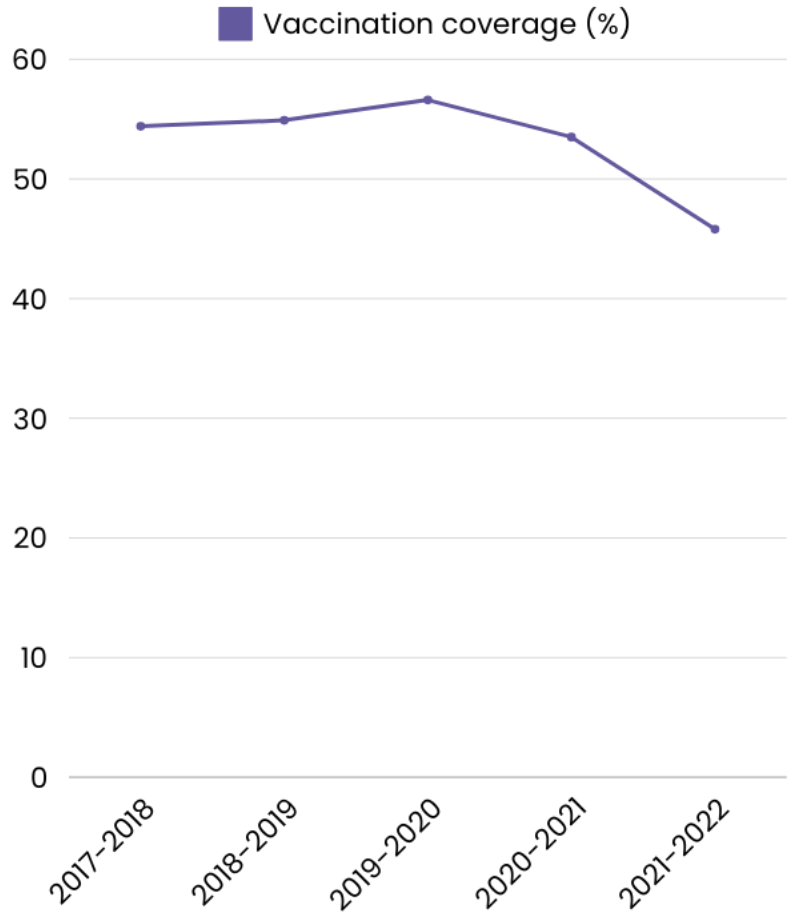
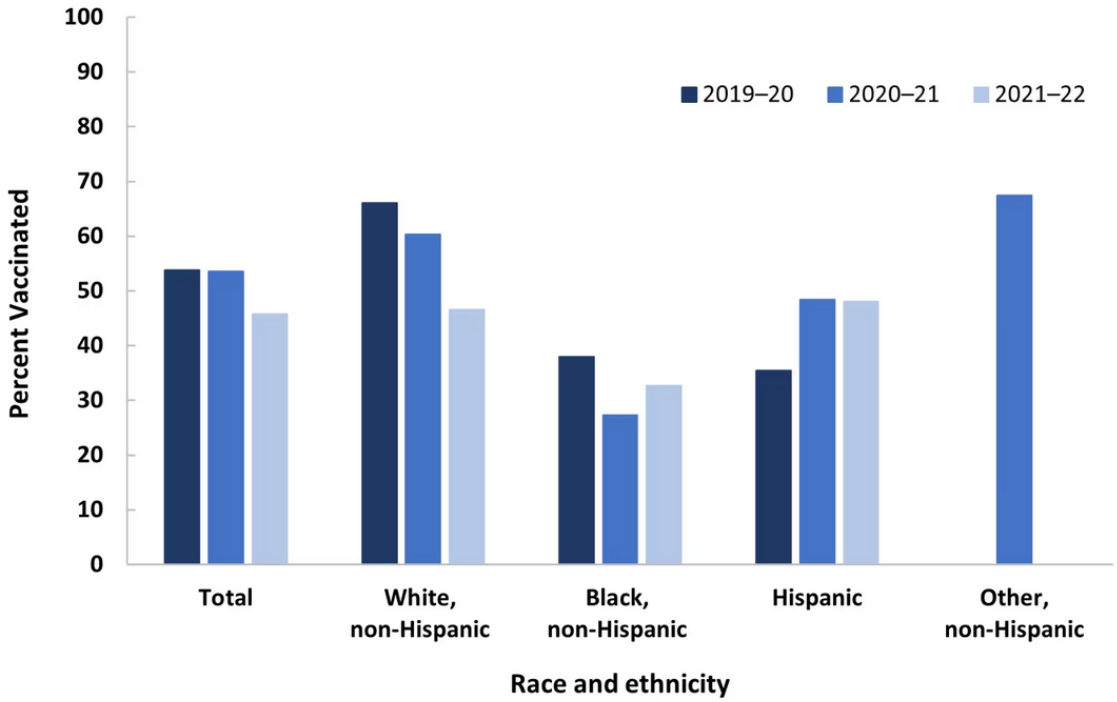
Tdap Vaccine Adherence

Despite overwhelming benefit, vaccine coverage remains poor and disparities in vaccine uptake need attention





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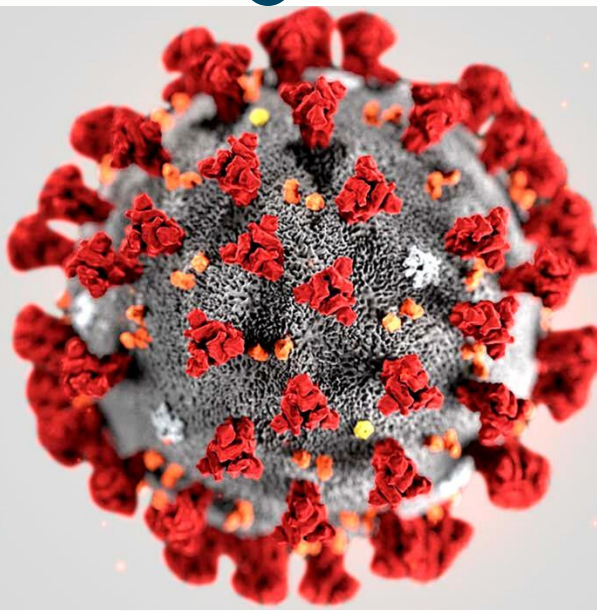
Current Recommendation

ACOG and ACIP recommend all pregnant persons receive vaccination against Tdap between 27-36 weeks gestation in every pregnancy

COVID-19



Virology

- COVID-19 is causes by the SARS-CoV-2 virus
- Positive-sense single-stranded RNA virus of the family coronaviruses
- Transmission via respiratory droplets

Disease burden

- Causes acute respiratory tract infections
- Major cause of morbidity and mortality in those infected
- In February 2023, 757,264,511 confirmed COVID-19 cases globally with a death toll of 6,850,594

Risk factors

- Tobacco use, immunocompromised, **pregnancy**, diabetes, heart, lung, and kidney disease

COVID causes worse outcomes in pregnancy

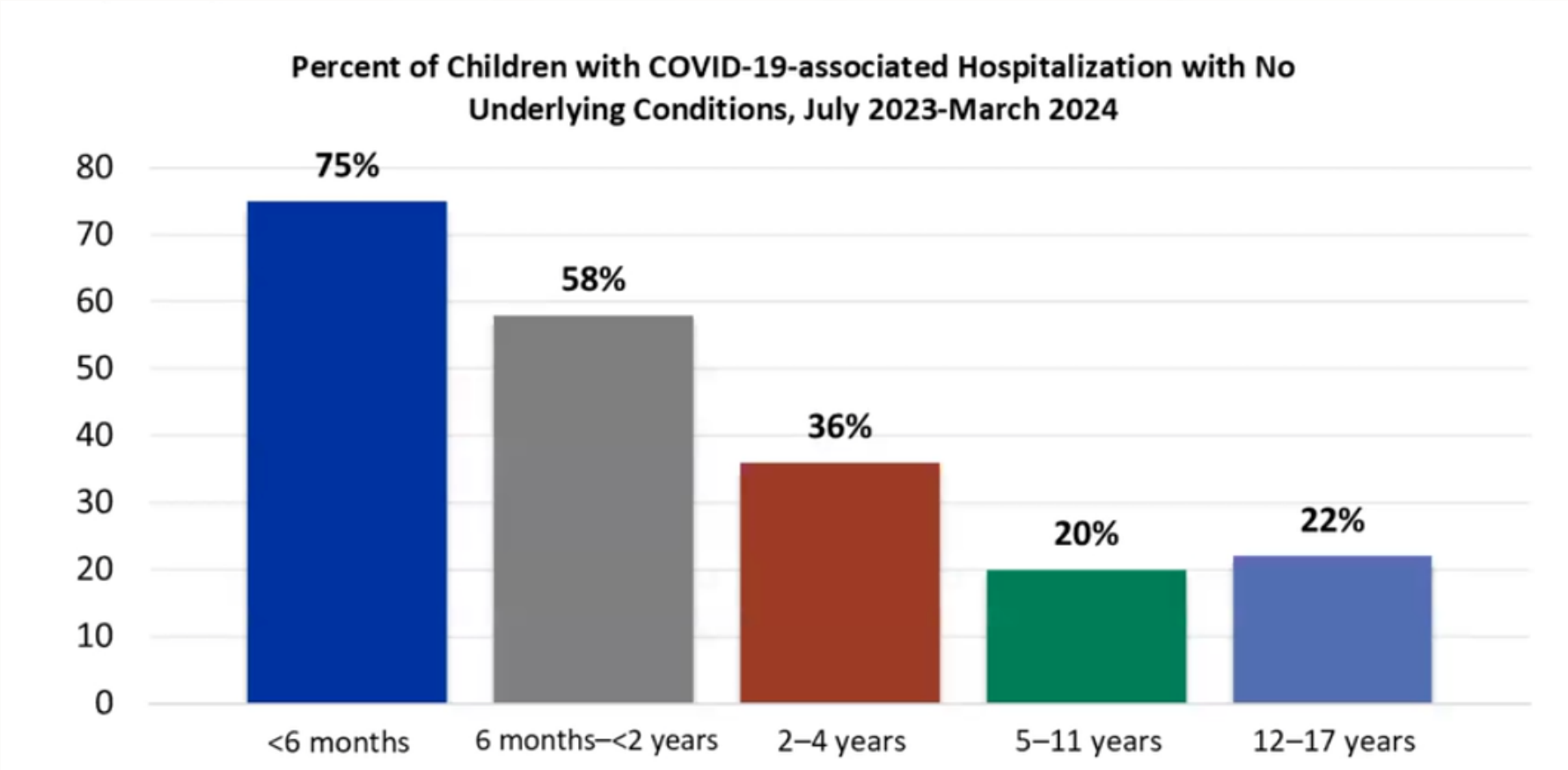
- 2x the rate of ICU admission
- 2x the rate of mechanical ventilation
- 50% higher rate of mortality

COVID-19 Severity	Cesarean Deliveries	RR of Cesarean Delivery (95% CI)	*P* (*P*-Trend=.001)
Asymptomatic	34 (33.3)	Reference	
Mild	22 (34.4)	1.03 (0.67–1.6)	.90
Severe	33 (54.1)	1.62 (1.1–2.3)	.01
Critical	11 (91.7)	2.8 (2.0–3.8)	<.001

COVID-19 Severity	Preterm Delivery (Less Than 37 wk of Gestation)	RR of Preterm Birth (95% CI)	*P* (*P*-Trend=.001)
Asymptomatic	11 (10.8)	Reference	
Mild	7 (10.9)	1.01 (0.41–3.6)	.97
Severe	11 (18.0)	1.67 (0.8–3.6)	.19
Critical	7 (58.3)	5.41 (2.6–11.3)	<.001

COVID-19 in Pediatric Population:

babies are at highest risk



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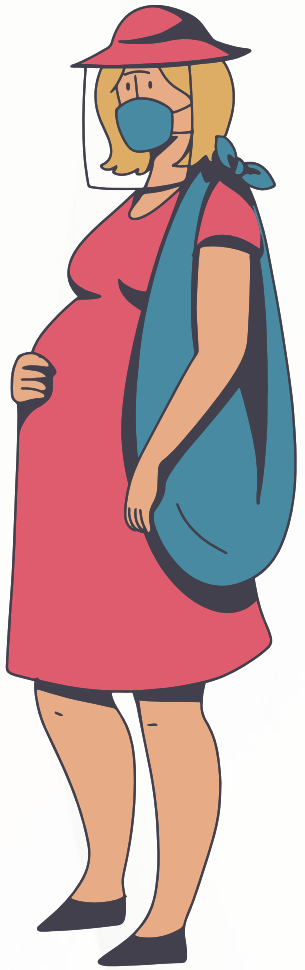
COVID-19 VACCINATION

- All pregnant people are recommended to receive vaccination against COVID-19
- 3 vaccines available: Pfizer-BioNTech, Moderna, or Novavax

- **Recommend all pregnant / postpartum patients get 1 dose updated Covid booster vaccine now available (annually)**
- **If recently had Covid: can wait 3 months to get updated Covid booster. If recently had 2023 booster, then can wait 2 months and get 2024 updated Covid booster**
- If patient has never been vaccinated: give 1 dose of mRNA vaccine (Pfizer and Moderna) or 2 doses of Novavax (8 weeks apart)
- If immunocompromised: patient should receive a 2nd dose updated Covid Booster (Novavax) (minimum of 8 weeks apart)
    - Pregnancy is not categorized as immunocompromised state
    - Malignancy, lung, heart, and liver disease



Benefits of COVID-19 Vaccination for pregnant patients and newborns

Maternal benefit

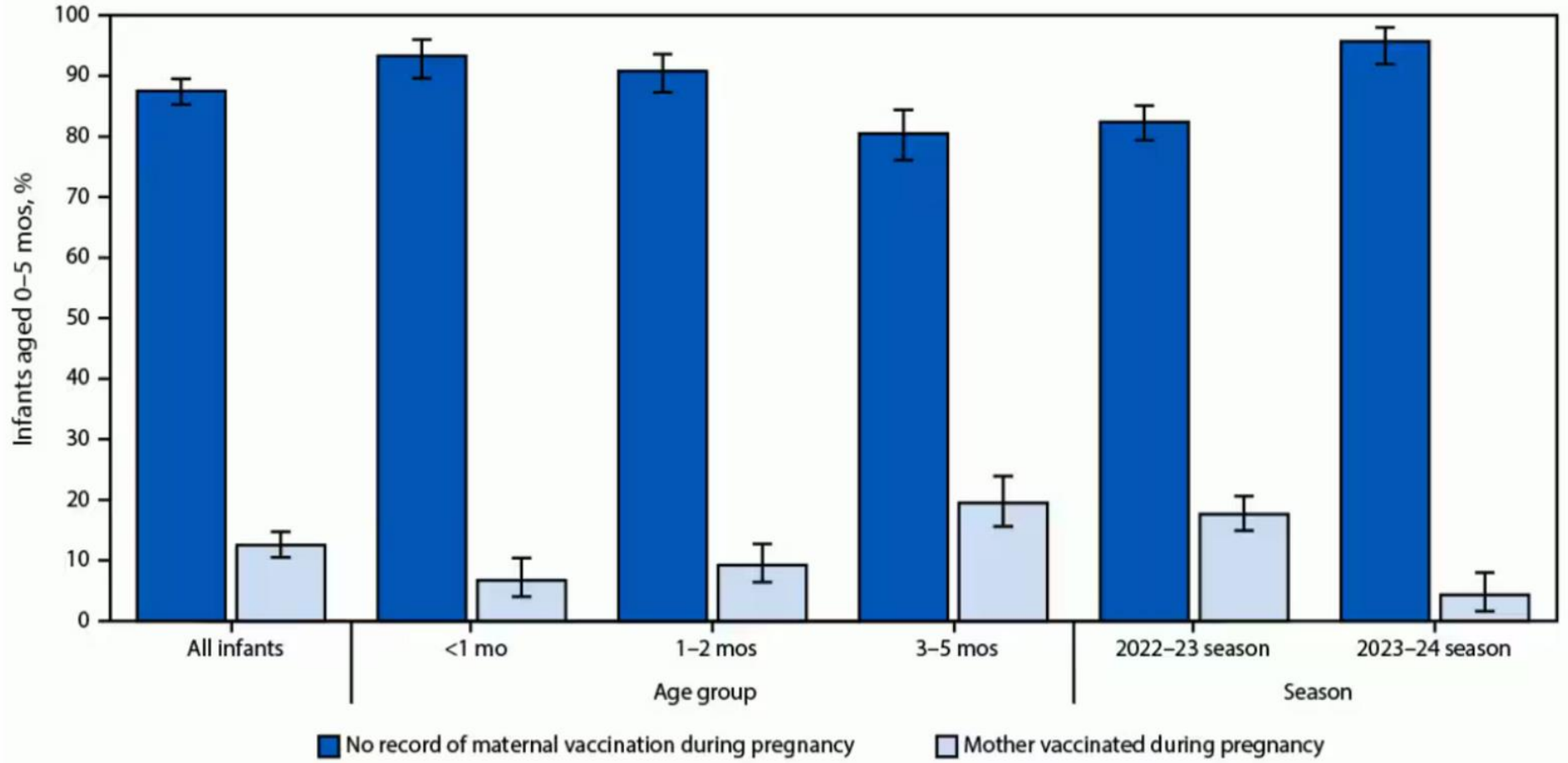
- Comparable immune response to non-pregnant individuals
- No increased risk for miscarriage or stillbirth
- **3-fold reduction in risk of infection and hospitalization**

Fetal and neonatal benefit

- Maternal immunization provides neonatal protection
- **50-80% reduction in risk of hospitalization, ICU admission, mechanical ventilation**

Maternal COVID-19 Vaccination Protects Newborns

Maternal Vaccination Status Among Infants age < 6 months hospitalized for COVID-19



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COVID-19 Vaccination reduces risk for mom and baby

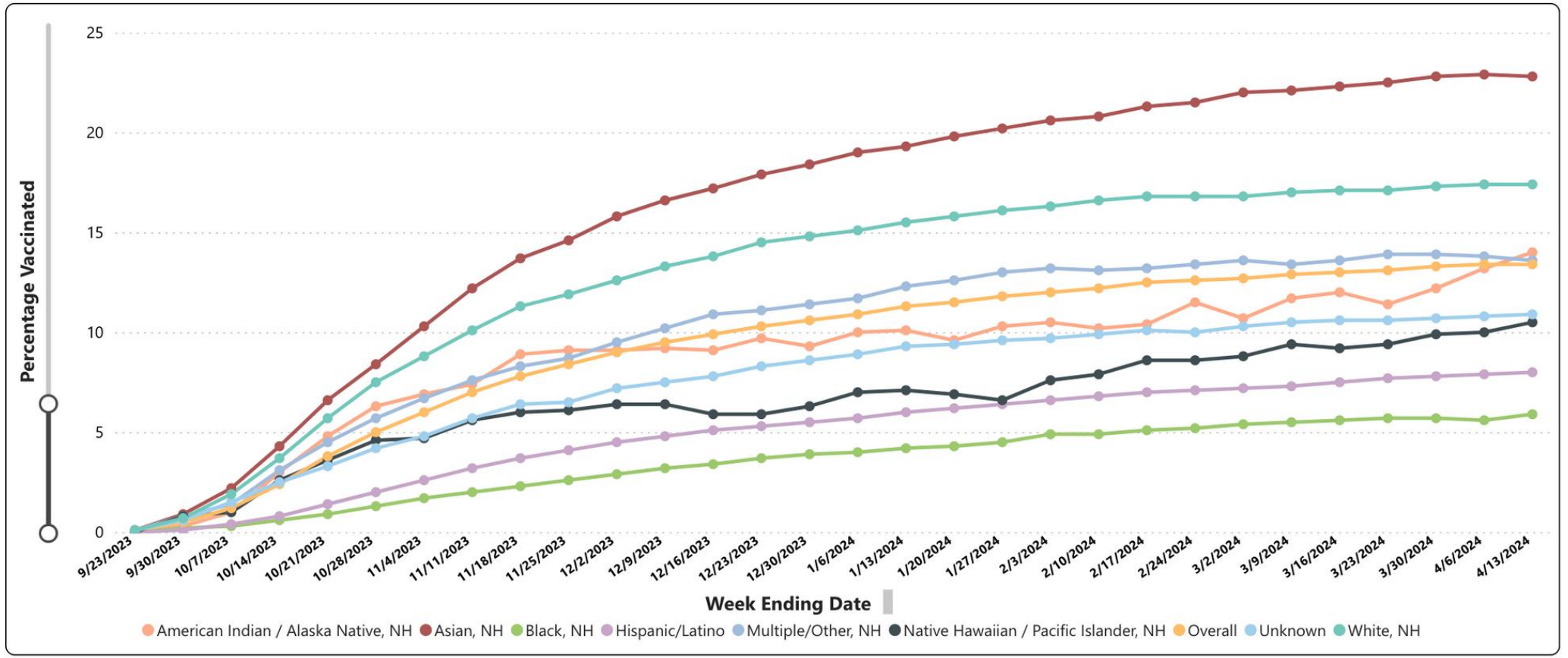
- "**None of the COVID-19 vaccines** available for use under emergency use authorization or U.S. Food and Drug Administration (FDA) license **causes infertility or spontaneous abortion**.
- There is **no evidence of adverse maternal or fetal effects from vaccinating pregnant individuals** with the COVID-19 vaccine, and a growing body of data demonstrates the safety of such use."

--ACOG

- mRNA COVID-19 vaccine in the first trimester was not associated with increased risks for birth defects

- **Vaccination with at least one Covid dose lowered the risk of adverse pregnancy-related and neonatal outcomes**

COVID-19 Vaccine Adherence



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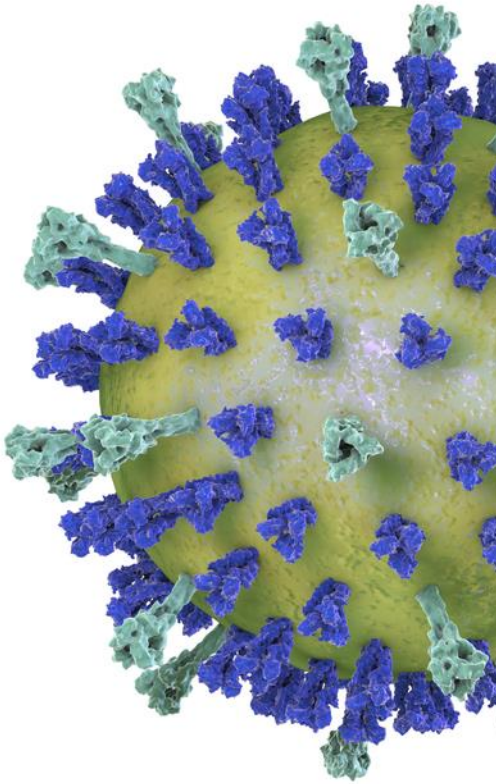
Current Recommendation

SMFM and ACOG recommend all pregnant persons receive vaccination against COVID-19 regardless of trimester, if not previously or adequately vaccinated (**should receive updated Covid booster vaccine to be adequately vaccinated**)

Respiratory Syncytial Virus

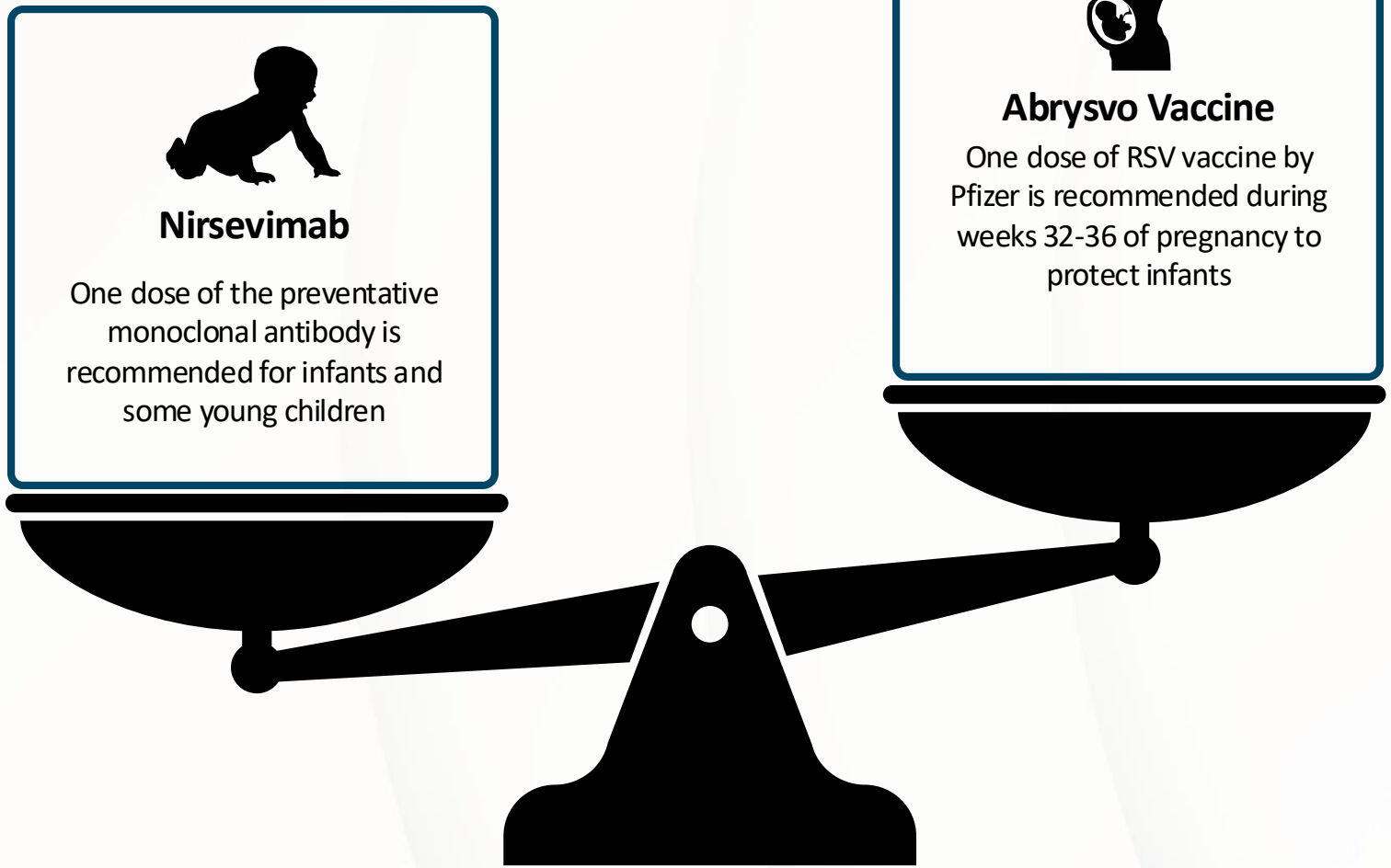


- Virology
  - Enveloped negative-strand RNA virus
  - Transmitted via respiratory droplets
  - Seasonal from September through April*

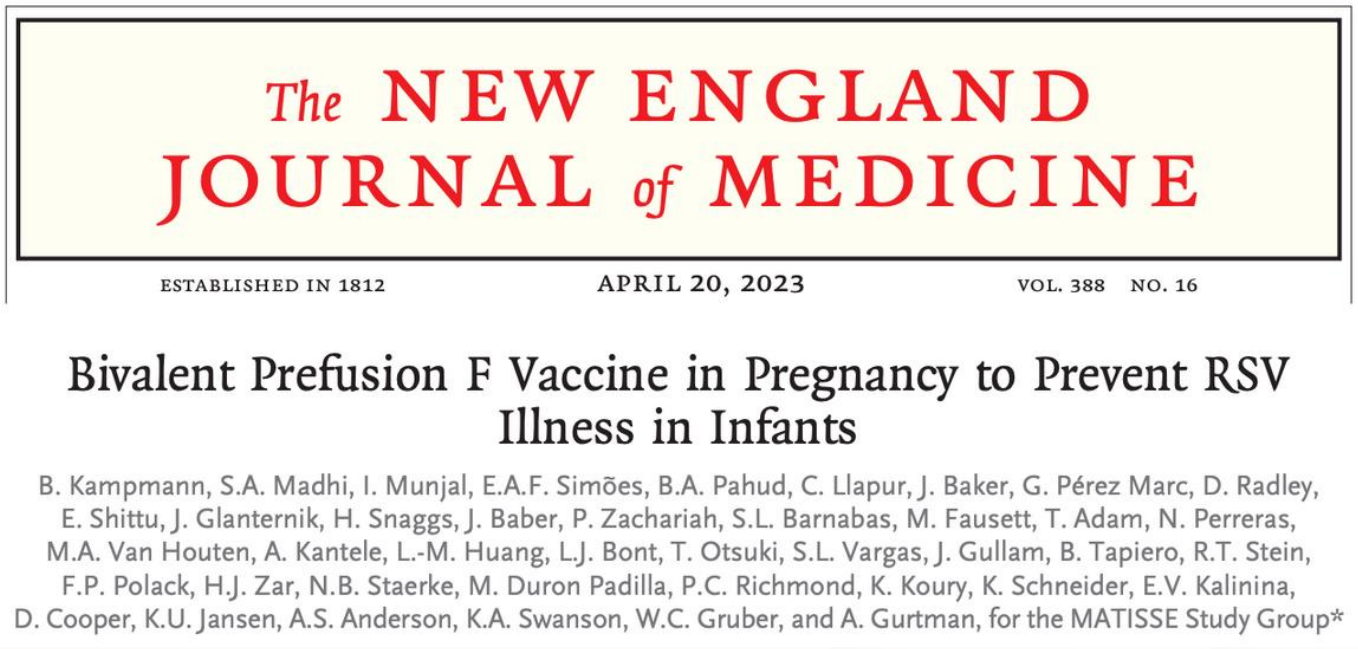
- Disease burden
  - Causes acute respiratory tract infections
  - **Major cause of morbidity and mortality in infants**
    - **68% of infants infected in 1st year and 97% by 2nd year**
  - **Leading cause of acute lower respiratory tract illness in infants less than 6 months of age**
  - **Leading cause of hospitalization in US infants**

- Risk factors
  - Lung disease, heart disease, prematurity

RSV Prevention



Methods



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Bivalent Prefusion F Vaccine in Pregnancy to Prevent RSV Illness in Infants

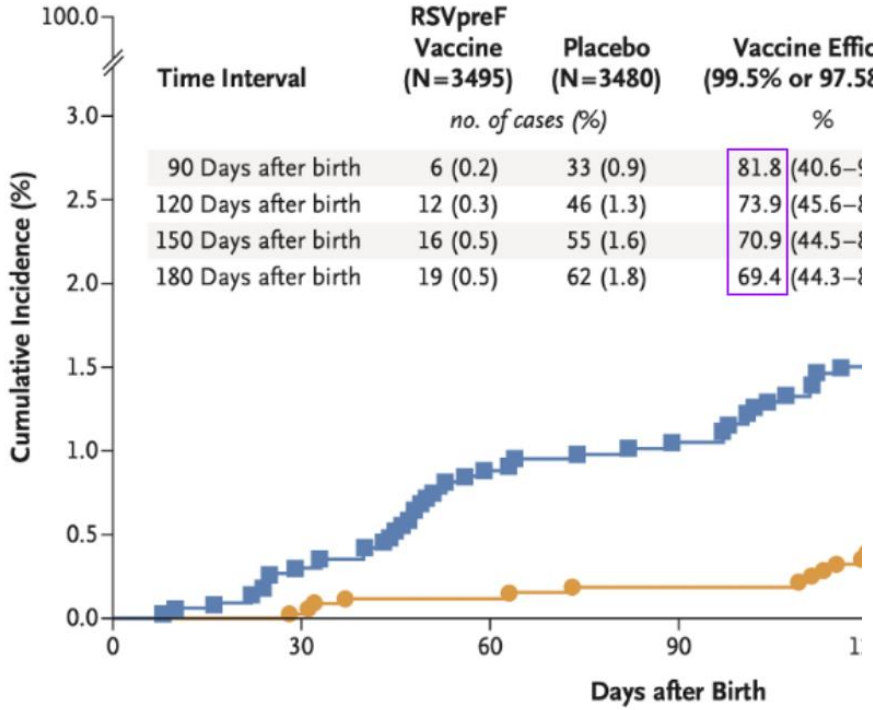
B. Kampmann, S.A. Madhi, I. Munjal, E.A.F. Simões, B.A. Pahud, C. Llapur, J. Baker, G. Pérez Marc, D. Radley, E. Shittu, J. Glanternik, H. Snaggs, J. Baber, P. Zachariah, S.L. Barnabas, M. Fausett, T. Adam, N. Perreras, M.A. Van Houten, A. Kantele, L.-M. Huang, L.J. Bont, T. Otsuki, S.L. Vargas, J. Gullam, B. Tapiero, R.T. Stein, F.P. Polack, H.J. Zar, N.B. Staerke, M. Duron Padilla, P.C. Richmond, K. Koury, K. Schneider, E.V. Kalinina, D. Cooper, K.U. Jansen, A.S. Anderson, K.A. Swanson, W.C. Gruber, and A. Gurtman, for the MATISSE Study Group*

- Phase 3, double-blind, randomized, placebo-controlled trial
- 18 countries over 4 RSV seasons
- Eligible participants:
  - Healthy, 49 years of age or younger, 24 - 36 weeks gestation
  - Uncomplicated, singleton pregnancy
- A single IM injection of 120 µg of RSVpreF vaccine (60 µg each of RSV A and RSV B antigens) or placebo

Maternal RSV Vaccine reduced risk of severe RSV for infants by 81.8%

A Medically Attended Severe RSV-Associated Lower Respiratory Tract Illness

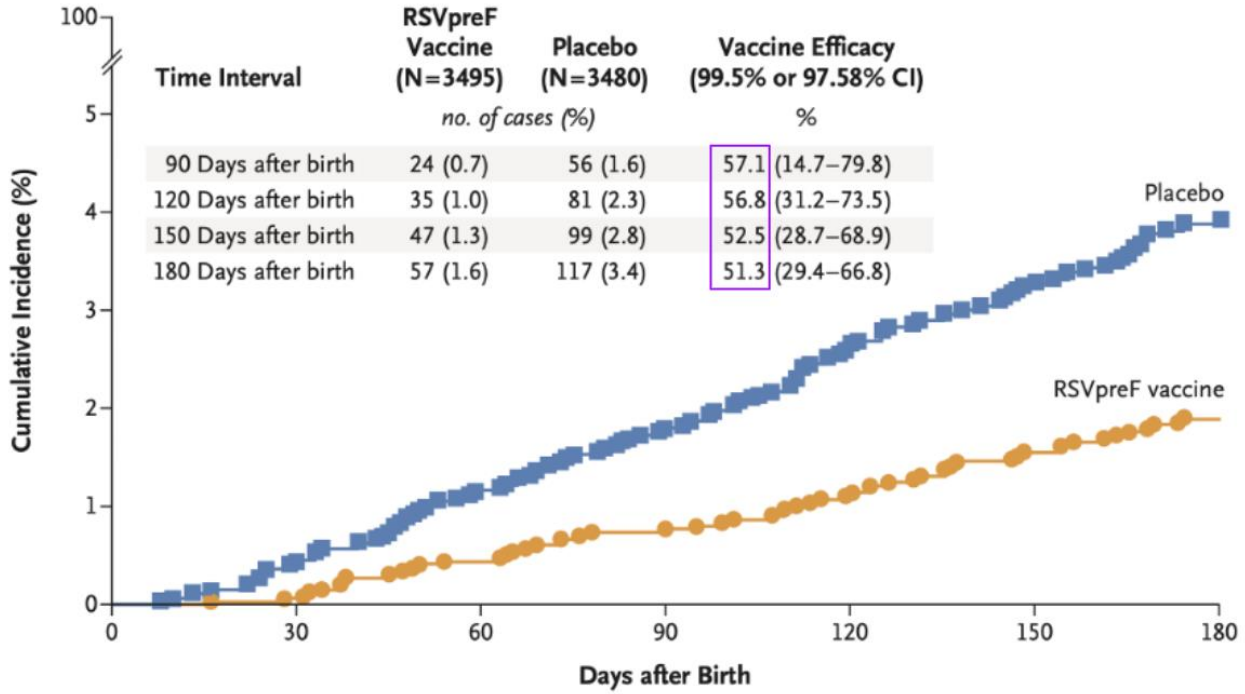
Time Interval	RSVpreF Vaccine (N=3495)	Placebo (N=3480)	Vaccine Efficacy (99.5% or 97.58% CI)
	no. of cases (%)		%
90 Days after birth	6 (0.2)	33 (0.9)	81.8 (40.6–9
120 Days after birth	12 (0.3)	46 (1.3)	73.9 (45.6–8
150 Days after birth	16 (0.5)	55 (1.6)	70.9 (44.5–8
180 Days after birth	19 (0.5)	62 (1.8)	69.4 (44.3–8



No. at Risk					
Placebo	3480	3292	2973	2899	28
RSVpreF vaccine	3495	3349	3042	2981	29

B Medically Attended RSV-Associated Lower Respiratory Tract Illness

Time Interval	RSVpreF Vaccine (N=3495)	Placebo (N=3480)	Vaccine Efficacy (99.5% or 97.58% CI)
	no. of cases (%)		%
90 Days after birth	24 (0.7)	56 (1.6)	57.1 (14.7–79.8)
120 Days after birth	35 (1.0)	81 (2.3)	56.8 (31.2–73.5)
150 Days after birth	47 (1.3)	99 (2.8)	52.5 (28.7–68.9)
180 Days after birth	57 (1.6)	117 (3.4)	51.3 (29.4–66.8)



No. at Risk							
Placebo	3480	3288	2964	2879	2804	2738	2700
RSVpreF vaccine	3495	3348	3035	2968	2898	2845	2792

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RSV vaccine given at 32-36 weeks

- FDA approved Pfizer RSVpreF vaccine to be administered during 32 - 36 weeks of pregnancy
- No significant difference in preterm birth rates (4% vaccine group vs 4.4% in control group)
- **Significant reduction in risk of severe RSV for 6 months**

Time period after birth	Trial dosing interval (24-36 weeks gestation) Vaccine efficacy (99.5% or 97.58% CI)	Approved dosing interval (32-36 weeks gestation) Vaccine efficacy (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)

On October 23, 2023 the CDC released a Health Alert Network communication regarding the limited supply of nirsevimab

Current Recommendation

ACOG and SMFM recommend Pfizer's RSVpreF vaccine (Abrysvo) for pregnant patients who are from 32 weeks to 36 weeks and six days of gestation for the prevention of severe RSV illness in infants.

Nirsevimab is the RSV vaccine for newborns, it was in short supply last year. Babies do not need this vaccine if maternal RSV vaccine was received during pregnancy

Patient Counseling

- Whopping cough, influenza, COVID, and RSV are 4 respiratory infections that can lead to severe illness and are leading causes of hospitalization for babies
- We now have vaccines for all 4 of these respiratory infections that when given during pregnancy reduce risk of severe illness and hospitalization for babies during first 6 months to a year
- CDC, ACOG, and SMFM recommend all 4 of these vaccines be given to all pregnant patients to reduce risk of severe newborn illness and neonatal hospitalization
- Give updated Covid and Flu vaccine when available, TDAP after 27 weeks, RSV between 32-36 weeks during RSV season (starts approx Sept 1)
- Maternal vaccination is the best way to reduce risk to newborns

Patient Counseling

The flu vaccine is

- Safe for you and your fetus during any trimester of pregnancy
- Effective at preventing severe flu illness during pregnancy

How does it protect my baby?

The flu vaccine creates antibodies that are passed to a fetus, which protect against the flu until a baby can get the flu vaccine at age 6 months.

The COVID-19 vaccine is

- Safe for you and your fetus during any trimester of pregnancy
- Effective at preventing severe illness from COVID-19

How does it protect my baby?

The COVID-19 vaccine creates antibodies that are passed to a fetus, which may protect against COVID-19 until a baby can get a COVID-19 vaccine at age 6 months.

The whooping cough vaccine (Tdap) is

- Safe for you and your fetus
- Recommended between 27 weeks and 36 weeks of each pregnancy

How does it protect my baby?

The Tdap vaccine creates antibodies that are passed to a fetus, which protect against whooping cough until a baby can get a whooping cough vaccine at age 2 months.

The Pfizer RSV vaccine is

- Safe for you and your fetus
- Recommended if you are between 32 and 36 weeks of pregnancy during RSV season (September through January)

How does it protect my baby?

The RSV vaccine creates antibodies that are passed to a fetus, which protect against RSV for the first 6 months after birth.

FAQ

Can these vaccines be administered together?

- Yes, the COVID-19, influenza, Tdap, and RSV vaccines can be co-administered.

When is the optimal time to vaccinate?

If I get COVID, should I still get the vaccine?

- Yes, CDC recommends delaying the vaccine dose by 3 months

Patient Education and Resources

Flu

- ACOG topic page
- Infographic: Top 3 Reasons Why You Need a Flu Vaccine
- Flu vaccine FAQ

Tdap

- Tdap vaccine FAQ
- Infographic: Top 3 Reasons Why You Need a Tdap Vaccine
- Tdap vaccine fast facts

COVID-19

- ACOG topic page
- Infographic: Top 3 Reasons Why You Need a COVID Vaccine
- COVID-19 FAQ from an OB/GYN

RSV

- ACOG topic page
- Infographic: Top 3 Reasons Why You Need a RSV Vaccine
- Infographic: Protecting Your Baby from RSV

Provider Resources

ACOG

Starting an Office Based Vaccine Program

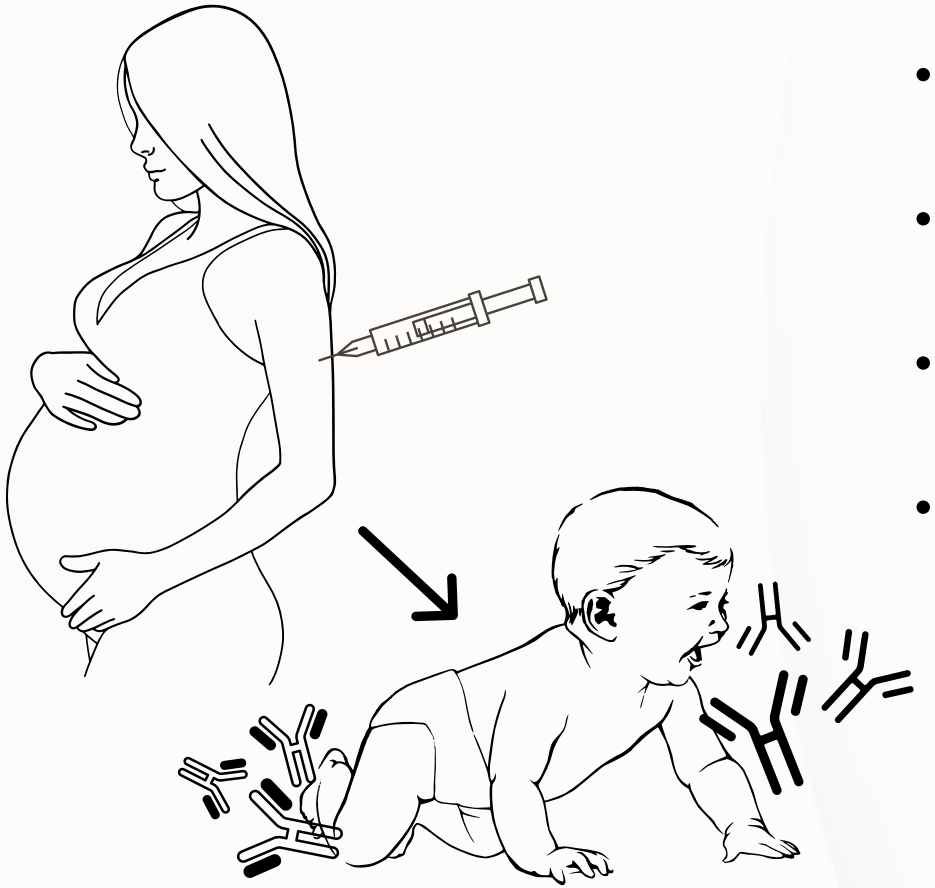
CDC

Maternal Vaccine Information for Healthcare Providers

ACOG

Practice Advisory: Maternal Immunization

Summary



- Maternal immunization protects both the patient and the infant
- Tdap, flu, RSV, COVID vaccines are recommended in pregnancy
- Healthcare providers play a crucial role in vaccine implementation
- Be a vaccine champion for yourself, your colleagues, your family, your friends, and your patients

THANK YOU!

Kiki Ogu MD
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Pediatric RSV Vaccine, Vaccine Access, and Vaccine Counseling

Leena Mithal, MD, MSCI

Lurie Children's Hospital

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Illinois Perinatal Quality Collaborative

Pediatric RSV Immunization

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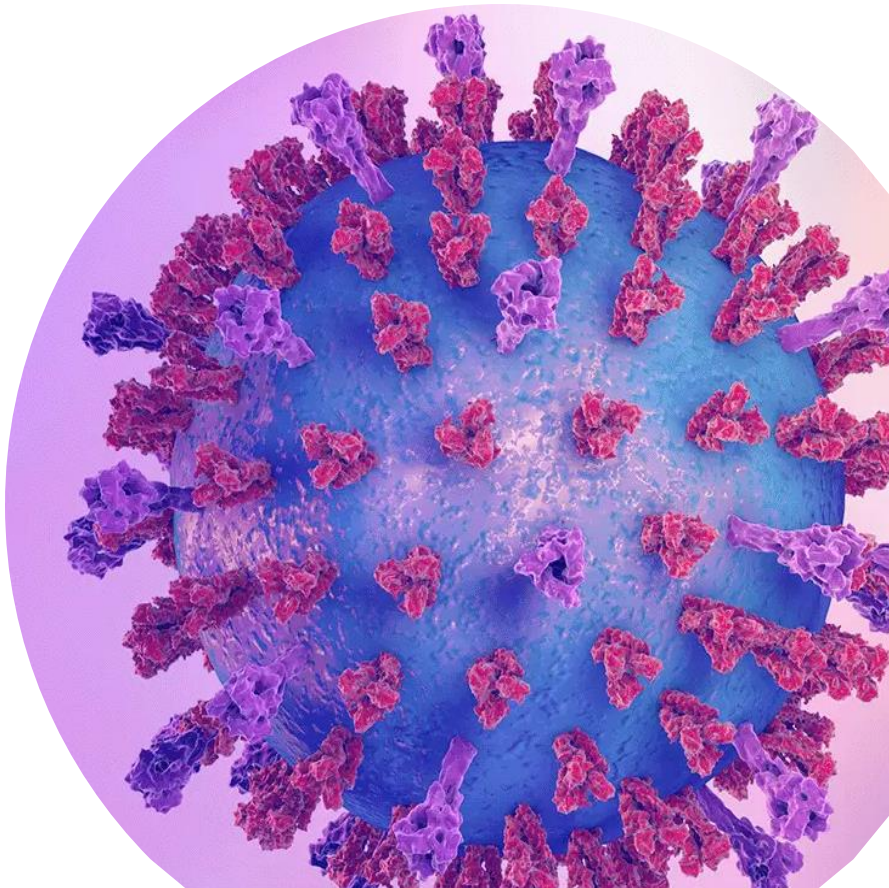
ILPQC October 2nd, 2024



Disclosure

- No financial relationships or conflicts of interest
- Society for Maternal Fetal Medicine Infectious Diseases and Emerging Threats Committee
- Grant funding

NIH

FRIENDS OF PRENTICE

THRASHER RESEARCH FUND

Gerber

Stanley Manne Children's Research Institute

NORTHWESTERN UNIVERSITY

Objectives

- Recommendation and availability of pediatric RSV immunizations
- RSV immunization utilization in 2023-24 season
- Counseling and uptake of pediatric RSV immunization

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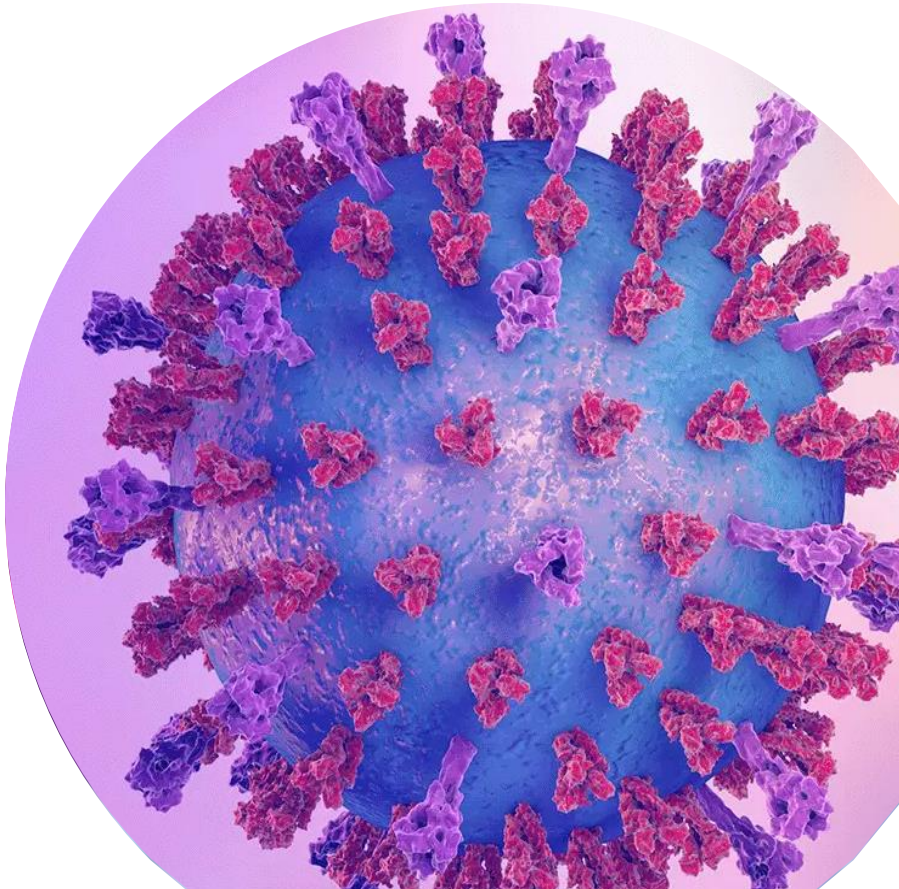
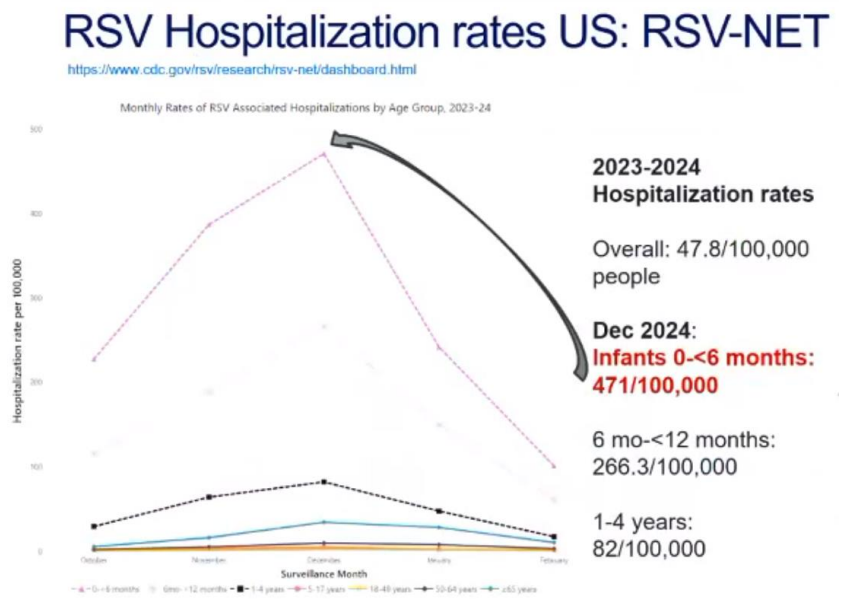
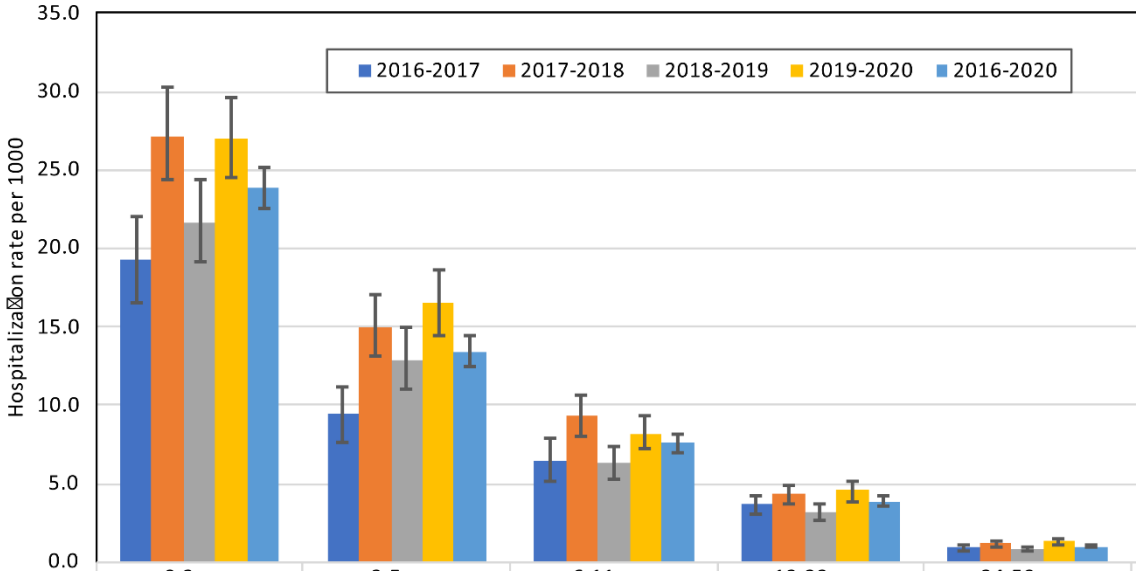
Recommendations and availability of pediatric RSV immunization



RSV is the leading cause of hospitalization in young infants

- RSV infection is nearly universal in first 2 years
- RSV is most common cause of hospitalization for U.S. infants
  - 2-3% of young infants under 6 months will be hospitalized for RSV
  - Majority previously healthy children





	0-2 mos	3-5 mos	6-11 mos	12-23 mos	24-59 mos
2016-2017	19.3	9.5	6.5	3.7	0.9
2017-2018	27.2	15.0	9.3	4.3	1.2
2018-2019	21.7	12.9	6.3	3.2	0.8
2019-2020	27.0	16.5	8.2	4.6	1.3
2016-2020	**23.8**	**13.4**	**7.6**	**3.9**	**1.0**

RSV-associated hospitalization rate per 1000 children
Curns et al. Pediatrics. 2024

Glezen et al, Arch Dis Child, 1986
Hall et al, Pediatrics 2013
Langley & Anderson, PIDJ 2011

RSV immunization for infants

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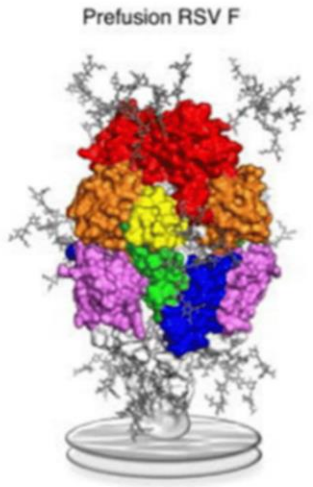
- Monoclonal antibody product (passive immunization)
- Seasonal monthly administration of Palivizumab (Synagis) decreases risk of RSV-associated hospitalizations among high-risk infants
- Nirsevimab (Beyfortus™) is a long-acting monoclonal antibody product
  - Given once per season
  - Protection expected to last at least 5 months
  - Expected to reduce severe RSV disease by 80%

DATE	Medication	Protein target	Dosing Cost	Population	Efficacy
1996	RSV IVIG	polyclonal	monthly X 5	High risk	40%
1998	Palivizumab	monoclonal preF & postF epitopes	monthly X 5 $10,000	High risk Preterm, CLD, CHD	55% (78% no CLD)
2023	Nirsevimab	monoclonal preF epitope Highly neutralizing	Once $500	**ALL** <8mo	**70-80%**



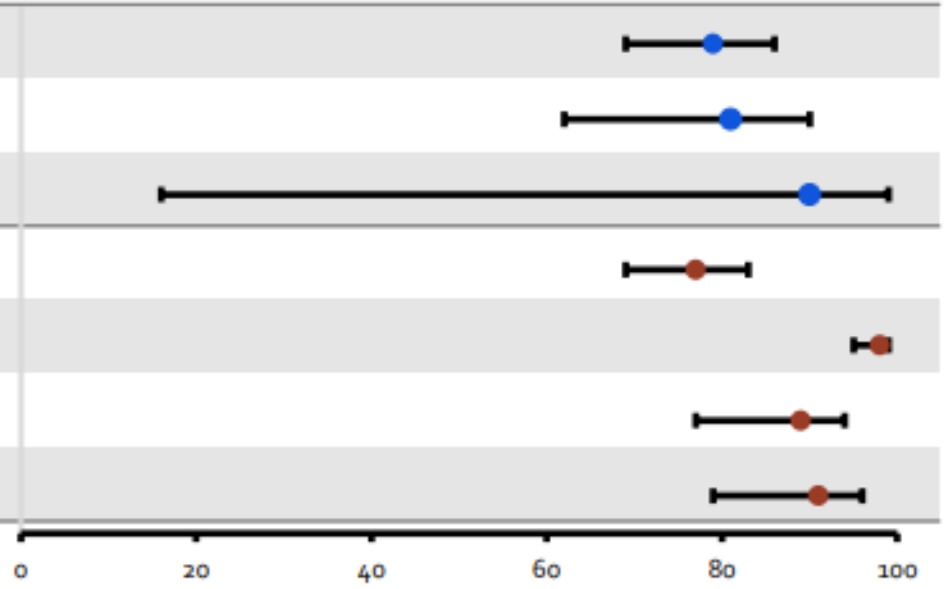
Nirsevimab:
50x neutralizing potency
3x longer half-life (70 days)
Dose once per season

Credit: Kelly Wade, MD PhD – PAS 2024

Summary of U.S. Data from 2023-2024 Season

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.

Summary of effectiveness of nirsevimab in infants. Payne, A. ACIP meeting Respiratory Syncytial Virus (RSV) Maternal/Pediatric vaccine https://stacks.cdc.gov/view/cdc/157872

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

RCT = randomized clinical trial | ARI = acute respiratory illness

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AAP and the Advisory Committee on Immunization Practices of the CDC recommends nirsevimab to prevent RSV lower respiratory tract disease for all infants younger than 8 months, and in infants with certain high-risk conditions age 8-19 months

Ideally administer October through March, depending on seasonality, local RSV activity, and other special circumstances

- All infants <8 months
  - Except whose pregnant parent received RSVpreF vaccine ≥14 days before giving birth
  - May be given even if parent vaccinated if parent has immunocompomising condition, infant may have lost transplacentally acquired antibodies, infant with substantially increased risk for severe RSV disease

- 8-19 months/during second RSV season
  - Infants and children with **chronic lung disease** of prematurity who required medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) at any time during the 6-month period before the start of the second RSV season
  - Infants and children who are **severely immunocompromised**
  - Infants and children with **cystic fibrosis** who have manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable) or have weight-for-length that is less than the 10th percentile
  - **American Indian and Alaska Native** children

Vaccine availability

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- Shortage is not expected this 2024-2025 season

- Administration setting
  - MMWR "Infants born during October through March should be administered nirsevimab in first week of life, *ideally during birth hospitalization*"
    - AAP and CDC efforts re: VFC enrollment for hospitals (for Hep B vaccine and nirsevimab)
    - Hospital systems efforts to lean on payors
  - Outpatient administration as soon as possible
  - Communication of maternal RSV vaccine status from obstetric to pediatric clinician

- Questions about ordering VFC doses should be directed to your state immunization program
- Questions about private/commercial ordering should be directed to Sanofi at 855-BEYFORTUS

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Considerations

Nirsevimab 	Direct receipt of antibodies rather than relying on transplacental transfer Protection may wane more slowly than maternal RSV vaccine Side effects are usually mild and resolve quickly; hypersensitivity reactions are uncommon but have been reported Delayed administration could leave the infant unprotected[1]

[1]Infants born during October through March should be administered nirsevimab in the first week of life – ideally during the birth hospitalization.

Preparing for Respiratory Virus Season (aap.org)

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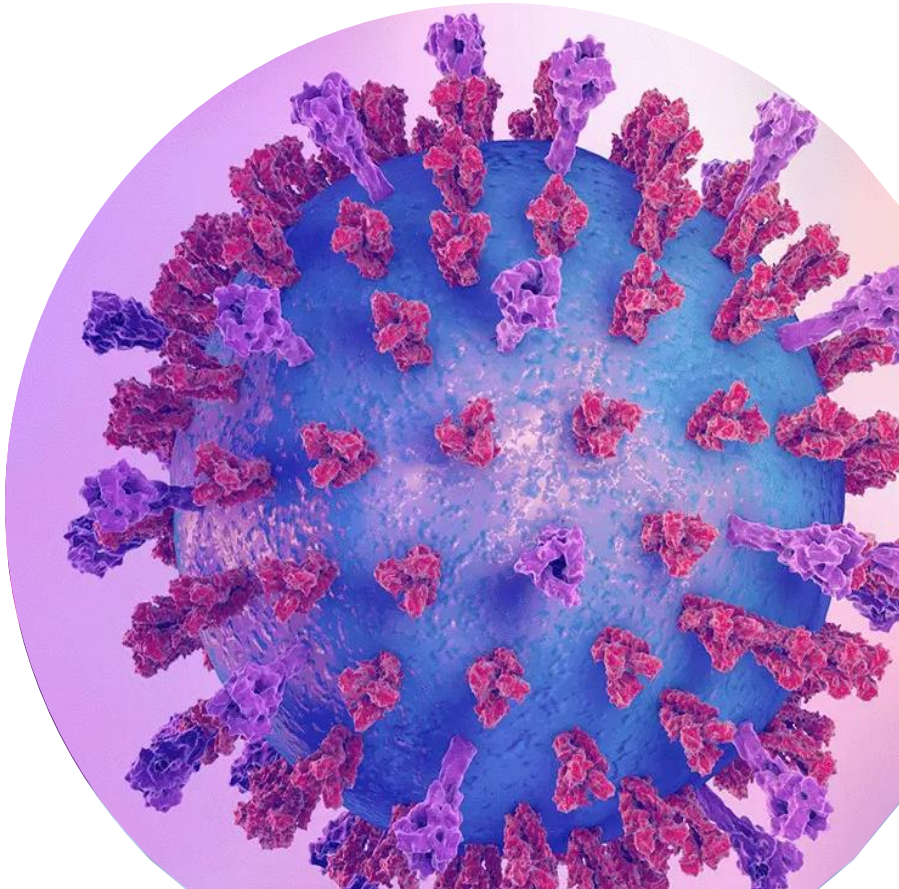
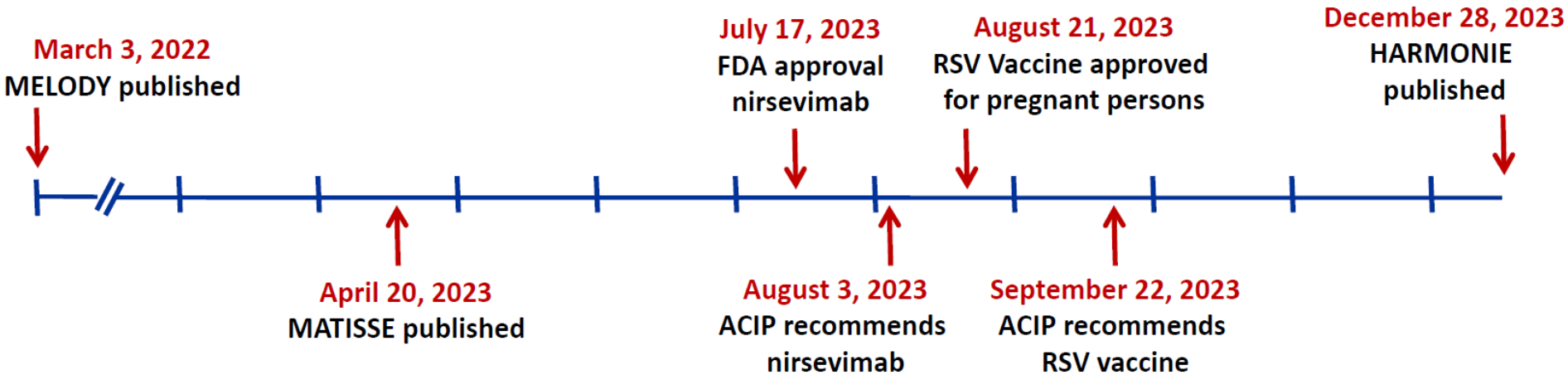
Utilization of RSV immunization 2023-2024 season





Multiple challenges:

- Timing of recommendations and product availability
  - Delayed start to administration
  - Shortage of nirsevimab October-December 2023
- Changing recommendations, nuanced communications
- Limited time to provide awareness to providers and patients
- Cost/reimbursement issues
- Coordination of maternal and infant preventive care
  - 14.2% received both maternal vaccine and nirsevimab

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CDC data: 2023-2024 season uptake

- Survey administered March 26–April 11, 2024
- 678 parents pregnant and vaccine eligible gestational age during Sept 2023-Jan 2024 timeframe
  - 32.6% received RSV vaccine
- 866 birthing parents with infants born August 2023-March 2024
  - 44.6% received nirsevimab
- In total, 56% of infants were protected against severe RSV disease by either product or both.

MMWR - Sept 26, 2024

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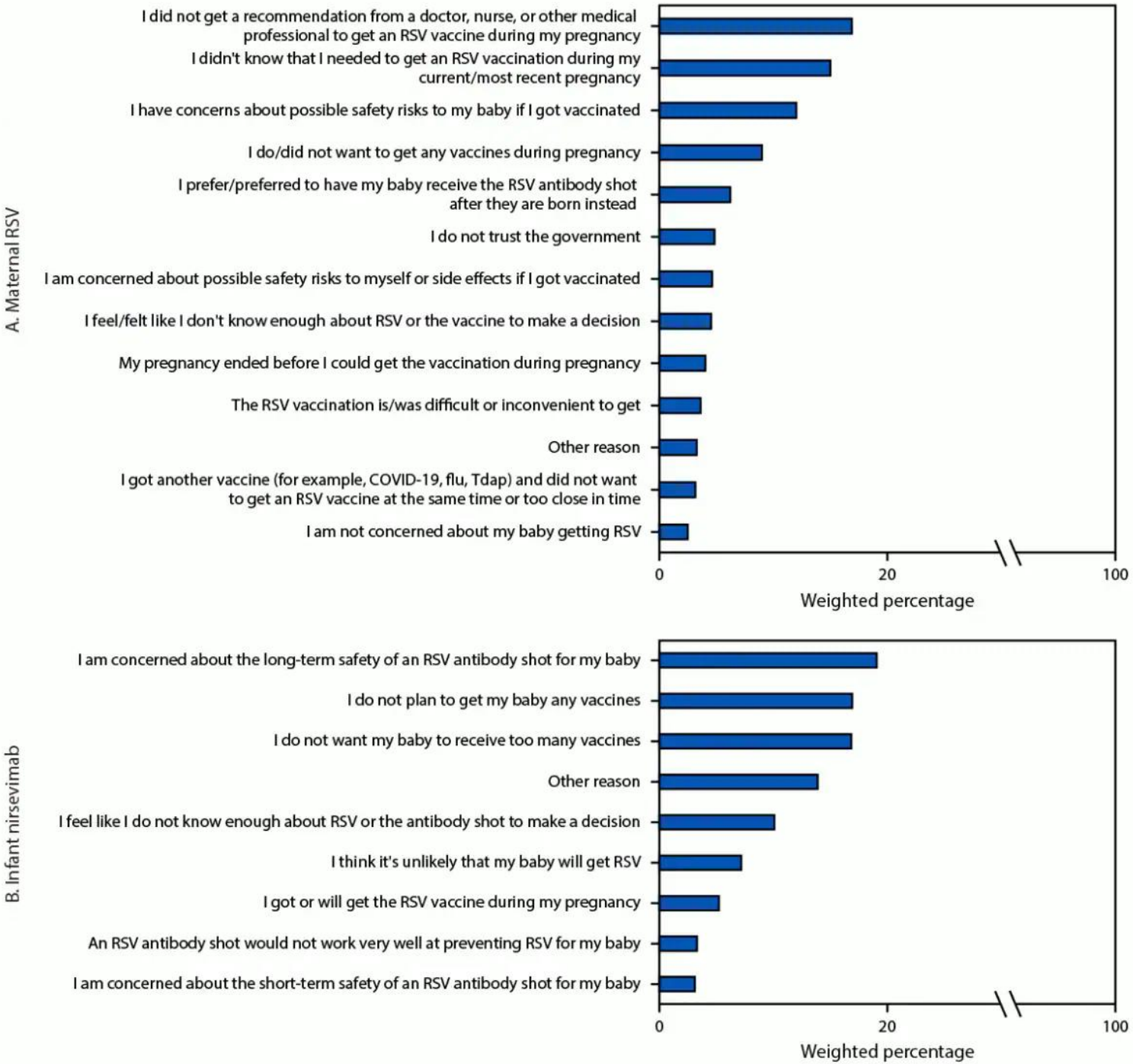

- **Provider recommendation for maternal vaccination or infant nirsevimab was associated with higher immunization coverage.**
- Lack of a provider recommendation was the main reason for not getting RSV vaccine.
- The main reason for definitely or probably not getting nirsevimab for infants was **concern about the long-term safety for the infant**.

MMWR - Sept 26, 2024

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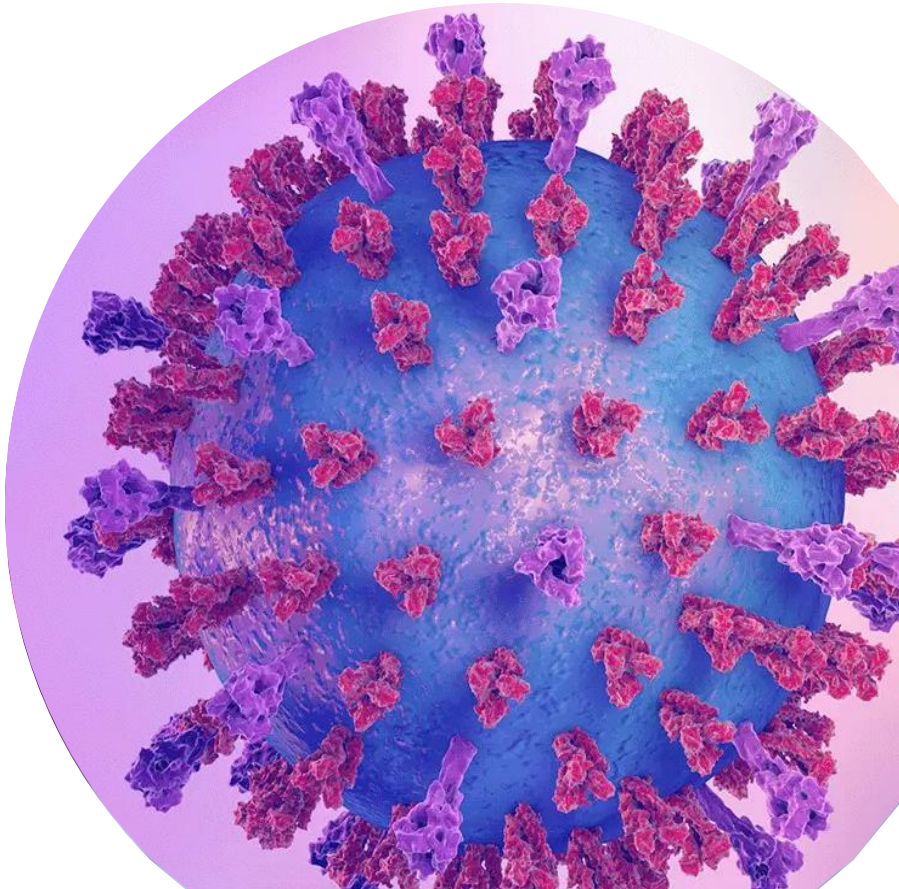
RSV immunization counseling and insights



Administration and safety

- Can be co-administered with routinely recommended vaccines

- Safety
  - "After getting an RSV preventive antibody, your child might have temporary pain, redness, swelling where the injection was given, or a rash."

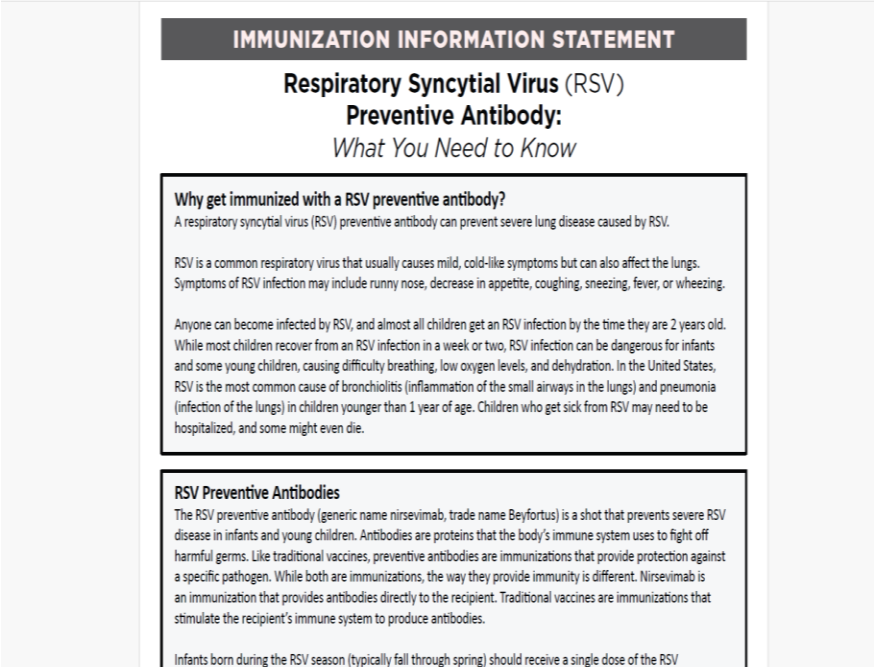
Pooled Analysis Preterm & Term Product Label

Adverse reactions: 1.2% (Nirsevimab) 97% mild-mod intensity

Adverse Reaction reported at an incidence higher than placebo	Nirsevimab	Placebo
Rash within 14 day post-dose	0.9%	0.6%
Injection site reaction within 7 days post dose	0.3%	0

Credit: Kelly Wade, MD PhD – PAS 2024

CDC has developed a "VIS-like" document called an Immunization Information Sheet on nirsevimab.



IMMUNIZATION INFORMATION STATEMENT

Respiratory Syncytial Virus (RSV)
Preventive Antibody:
What You Need to Know

Why get immunized with a RSV preventive antibody?
A respiratory syncytial virus (RSV) preventive antibody can prevent severe lung disease caused by RSV.

RSV is a common respiratory virus that usually causes mild, cold-like symptoms but can also affect the lungs. Symptoms of RSV infection may include runny nose, decrease in appetite, coughing, sneezing, fever, or wheezing.

Anyone can become infected by RSV, and almost all children get an RSV infection by the time they are 2 years old. While most children recover from an RSV infection in a week or two, RSV infection can be dangerous for infants and some young children, causing difficulty breathing, low oxygen levels, and dehydration. In the United States, RSV is the most common cause of bronchiolitis (inflammation of the small airways in the lungs) and pneumonia (infection of the lungs) in children younger than 1 year of age. Children who get sick from RSV may need to be hospitalized, and some might even die.

RSV Preventive Antibodies
The RSV preventive antibody (generic name nirsevimab, trade name Beyfortus) is a shot that prevents severe RSV disease in infants and young children. Antibodies are proteins that the body's immune system uses to fight off harmful germs. Like traditional vaccines, preventive antibodies are immunizations that provide protection against a specific pathogen. While both are immunizations, the way they provide immunity is different. Nirsevimab is an immunization that provides antibodies directly to the recipient. Traditional vaccines are immunizations that stimulate the recipient's immune system to produce antibodies.

Infants born during the RSV season (typically fall through spring) should receive a single dose of the RSV

Increasing vaccine confidence and uptake

- A strong recommendation from a trusted healthcare provider is the best predictor of vaccination.

- Other tools to increase vaccine coverage:
  - Patient facing reminders/education
  - Clinical decision support tools for providers
  - Continue to recommend immunizations to patients, even if they declined previously

Be specific. Be clear. Be attentive. Try again.

Resources and references:

- AAP RSV FAQs - https://www.aap.org/en/patient-care/respiratory-syncytial-virus-rsv-prevention/nirsevimab-frequently-asked-questions/?_ga=2.17064049.93639630.1727730750-1753099774.1723127476

- CDC - Maternal Respiratory Syncytial Virus Vaccination and Receipt of Respiratory Syncytial Virus Antibody (Nirsevimab) by Infants Aged 8 Months - United States, April 2024 | MMWR (cdc.gov)

- AAP webinar - Preparing for Respiratory Virus Season (aap.org)

- AAP Red Book:
  - New webinar series https://publications.aap.org/redbook/resources/15686?autologincheck=redirected
  - https://publications.aap.org/redbook/resources/25379/AAP-Recommendations-for-the-Prevention-of-RSV

Vaccines for Children Program

Leslie Caldarelli, MD

ILPQC and Lurie Children's Hospital

ILPQC
Illinois Perinatal Quality Collaborative

What is the Vaccines for Children program?

- The Vaccines for Children (VFC) program is a federally funded, jurisdiction-administered program which provides vaccines recommended for children and adolescents by the Advisory Committee on Immunization Practices (ACIP) at no cost to eligible individuals from birth through age 18 years.
- Children and adolescents are eligible for VFC vaccines if they are:
    - Eligible for Medicaid
    - Uninsured or underinsured
    - American Indian or Alaska Native

AIM Association of Immunization Managers

- According to CDC estimates, between 1994 and 2021, the VFC program helped to prevent:
  - **472 million illnesses**
  - **~30 million hospitalizations**
  - **> 1,000,000 deaths,**
  - **And saved nearly $2.2 million in total societal costs**

Association of Immunization Managers

How does the VFC program work?

- The CDC purchases vaccines from manufacturers at discounted rates and distributes them to VFC enrolled healthcare providers at the direction of the 64 state, local, and territorial immunization programs. These immunization programs are usually housed within the department of health.
- Immunization programs enroll healthcare providers—physician offices, hospitals, and pharmacies—into the VFC program and provide VFC vaccines to them at no cost.
- VFC program providers administer vaccines to eligible children and adolescents at no cost to families. Providers can charge a set fee to administer each vaccination, but if the family cannot afford the fee, patients cannot be turned away due to inability to pay.
- All VFC providers follow and enforce the federal and jurisdiction-specific VFC program requirements.

AIM Association of Immunization Managers

Why should birthing institutions participate?

- Ensures equitable access to immunizations.
- Saves money for hospitals
- Protects newborns at the first opportunity
- Save lives and reduces the burden on the healthcare system

AIM Association of Immunization Managers

What are the requirements to participate in the VFC program?

- VFC program requirements vary by jurisdiction, but all jurisdictions require providers to sign an agreement annually or biannually, participate in an enrollment visit and subsequent educational visits with trained public health staff
- Screen and document VFC eligibility at each vaccination encounter
- Demonstrate capacity to properly order, receive and manage vaccines
- The provider or facility must identify a vaccine coordinator

AIM Association of Immunization Managers

Are there special rules for birthing institutions?

- Birthing institutions are not required to carry all vaccines recommended by the ACIP to participate in VFC.
- Birthing institutions qualify as “specialty providers” that may stock and administer only those immunizations recommended at birth.
  - nirsevimab (RSV for newborns)
  - hepatitis B vaccine
- VFC and commercial vaccines can be stored in the same storage unit
- Birthing institutions are able to complete enrollment virtually

AIM Association of Immunization Managers

How to enroll?

- The Illinois Department of Public Health is responsible for administering the VFC program within the state excluding the City of Chicago.
- The Chicago Department of Public Health is responsible for administering the VFC program within Chicago city limits.
- To learn more about the Vaccines for Children program and to enroll visit Vaccines for Children Program Illinois:

https://www.immunizationmanagers.org/content/uploads/2024/05/Birthing-Institutions-and-the-Vaccines-for-Children-Program_050124.pdf

Vaccines During Pregnancy

Vaccines are recommended during pregnancy to protect against serious illnesses. The most common vaccines given in pregnancy include the flu, Tdap, COVID-19, and RSV (respiratory syncytial virus).

These vaccines can keep you healthy and help protect your baby after birth.

The flu vaccine is

- Safe for you and your fetus during any trimester of pregnancy
- Effective at preventing severe flu illness during pregnancy

How does it protect my baby?

The flu vaccine creates antibodies that are passed to a fetus, which protect against the flu until a baby can get the flu vaccine at age 6 months.

The whooping cough vaccine (Tdap) is

- Safe for you and your fetus
- Recommended between 27 weeks and 36 weeks of each pregnancy

How does it protect my baby?

The Tdap vaccine creates antibodies that are passed to a fetus, which protect against whooping cough until a baby can get a whooping cough vaccine at age 2 months.

The COVID-19 vaccine is

- Safe for you and your fetus during any trimester of pregnancy
- Effective at preventing severe illness from COVID-19

How does it protect my baby?

The COVID-19 vaccine creates antibodies that are passed to a fetus, which may protect against COVID-19 until a baby can get a COVID-19 vaccine at age 6 months.

This important patient education handout covers all 4 vaccines recommended in pregnancy to protect birthing person and newborns. Please share with all outpatient prenatal care locations and pregnant patients.

EVERTHRIVE ILLINOIS
CHAMPIONS FOR HEALTH EQUITY

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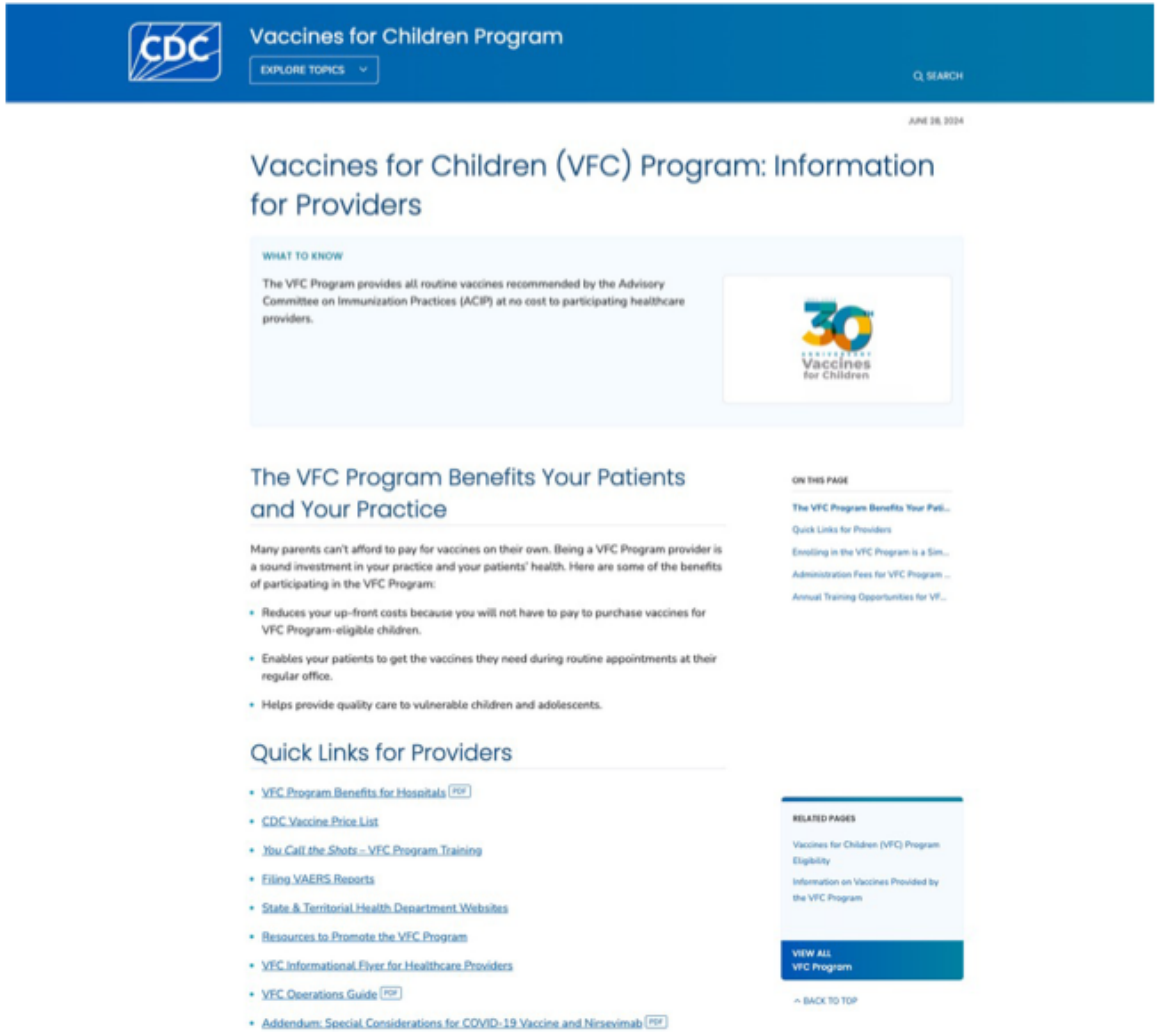
Illinois Perinatal Quality Collaborative

Resources availble in English and Spanish!

Covid 19

Flu

Vaccines For Children (VFC)



Vaccines for Children Program

EXPLORE TOPICS

SEARCH

JUNE 28, 2024

Vaccines for Children (VFC) Program: Information for Providers

WHAT TO KNOW

The VFC Program provides all routine vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) at no cost to participating healthcare providers.

The VFC Program Benefits Your Patients and Your Practice

Many parents can't afford to pay for vaccines on their own. Being a VFC Program provider is a sound investment in your practice and your patients' health. Here are some of the benefits of participating in the VFC Program:

- Reduces your up-front costs because you will not have to pay to purchase vaccines for VFC Program-eligible children.
- Enables your patients to get the vaccines they need during routine appointments at their regular office.
- Helps provide quality care to vulnerable children and adolescents.

ON THIS PAGE

The VFC Program Benefits Your Pati...
Quick Links for Providers
Enrolling in the VFC Program is a Sim...
Administration Fees for VFC Program ...
Annual Training Opportunities for VF...

Quick Links for Providers

- VFC Program Benefits for Hospitals PDF
- CDC Vaccine Price List
- *You Call the Shots* - VFC Program Training
- Filing VAERS Reports
- State & Territorial Health Department Websites
- Resources to Promote the VFC Program
- VFC Informational Flyer for Healthcare Providers
- VFC Operations Guide PDF
- Addendum: Special Considerations for COVID-19 Vaccine and Nirsevimab PDF

RELATED PAGES

Vaccines for Children (VFC) Program Eligibility
Information on Vaccines Provided by the VFC Program

VIEW ALL VFC Program

BACK TO TOP

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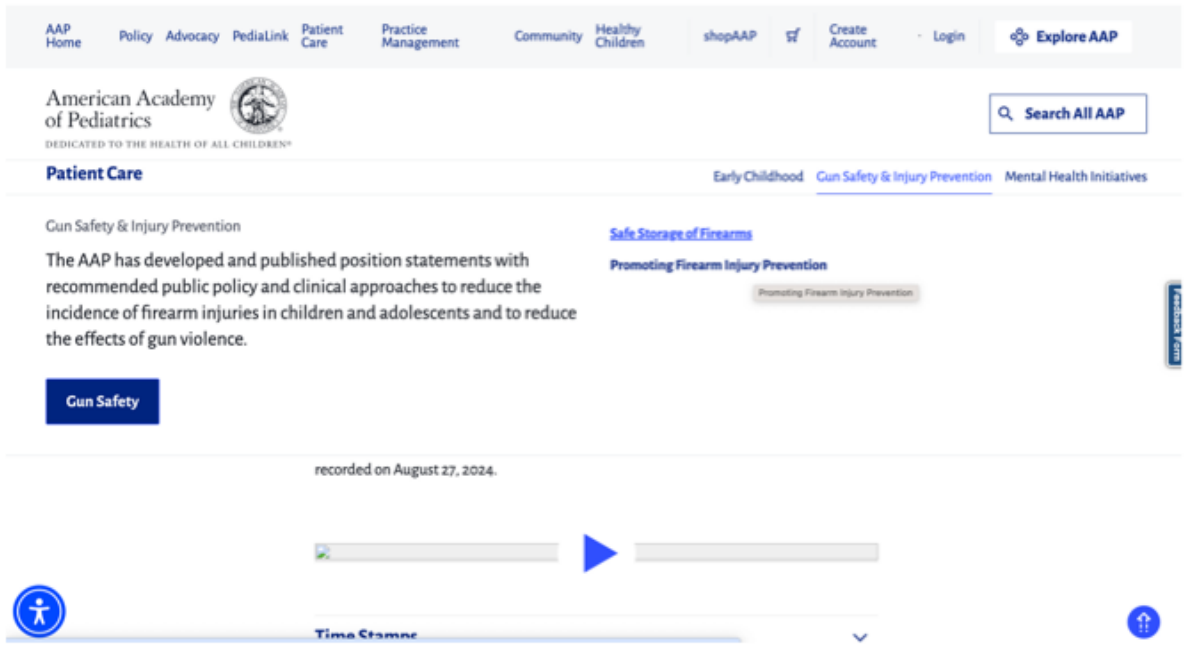
Preparing for Respiratory Virus Season



[Register here!]