Bump Up Provider Confidence: The Critical Role of Vaccines in Pregnancy

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Disclosure

- Dr. Rebekah Tompkins has no relevant financial relationships with ineligible companies to disclose.

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PHARMACY EDUCATION

Objectives:

Upon completion of this course, participants should be able to:

1. Recognize current recommendations for vaccination during pregnancy, with a focus on Tdap, influenza, COVID-19, and RSV vaccines.
2. Recall current recommendations for RSV immunization in infants.
3. Describe the burden of vaccine-preventable diseases and benefits of vaccination for pregnant people and their infants.
4. Review tools to increase provider confidence in making a strong recommendation for vaccination and addressing patient vaccine-related questions.

Changes to the body during pregnancy:

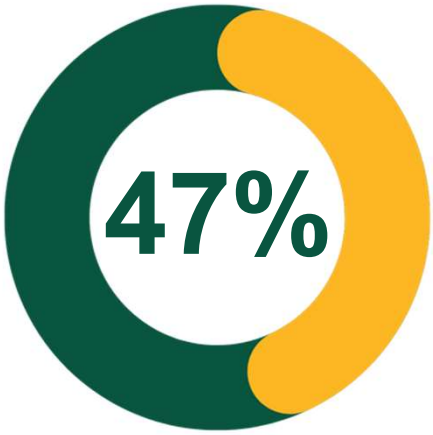
Immune system suppression is common during pregnancy, which makes patients more susceptible to vaccine-preventable diseases, like flu and COVID-19.

Many changes occur in the respiratory and circulatory systems during pregnancy. Hormones and physical changes due to the growing fetus can affect the upper and lower respiratory tracts and heart.

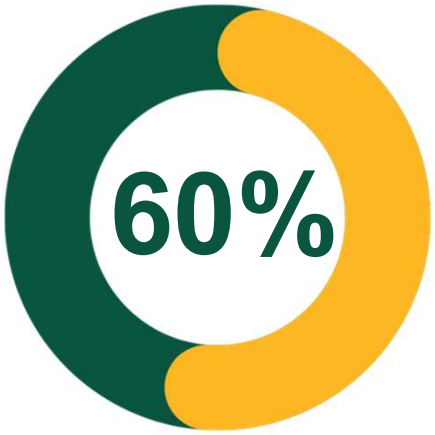
Vaccination during pregnancy can help to protect both mom and baby from vaccine-preventable diseases.

CHOP VEC, 2022; CDC 2024

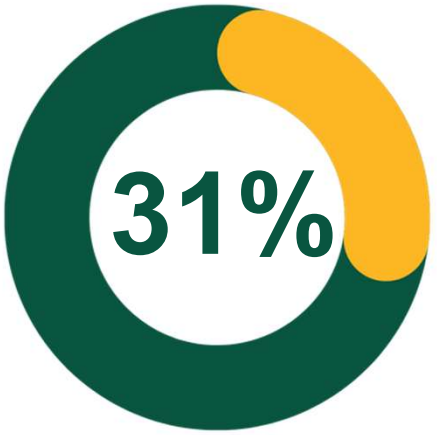
During the 2023-24 flu season



women received flu vaccination before or during pregnancy



women with a recent live birth received Tdap vaccination during pregnancy



women received an updated COVID-19 vaccination before or during pregnancy

Kahn et al, FluVaxView, 2024

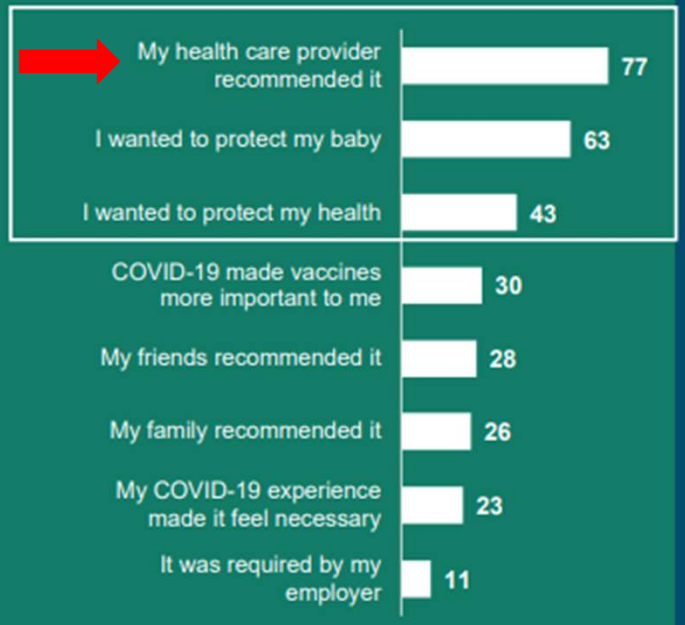
A recent review suggests *vaccine safety* as the most commonly cited obstacle for COVID, flu, and pertussis vaccination during pregnancy.

CDC, 2023; Nichol et al, PLOS ONE, 2023; Kahn et al, FluVaxView, 2024

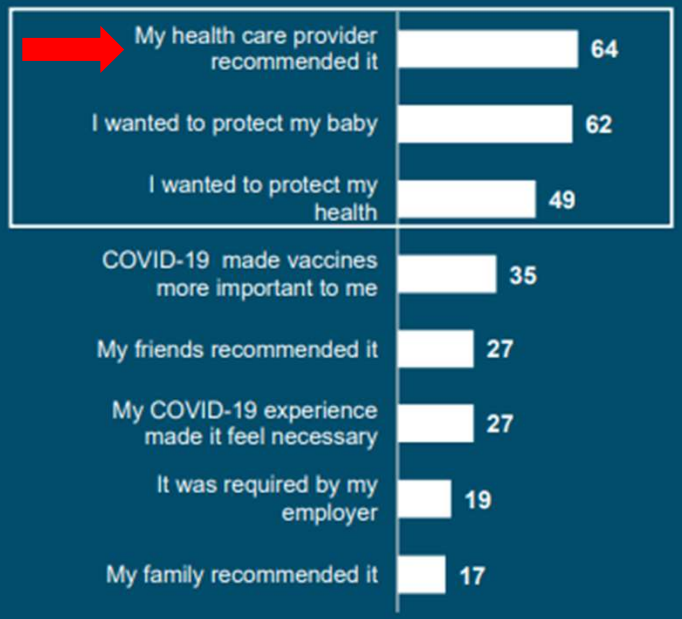
Health care providers' recommendations and a desire to protect the baby's health drive vaccine decisions

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

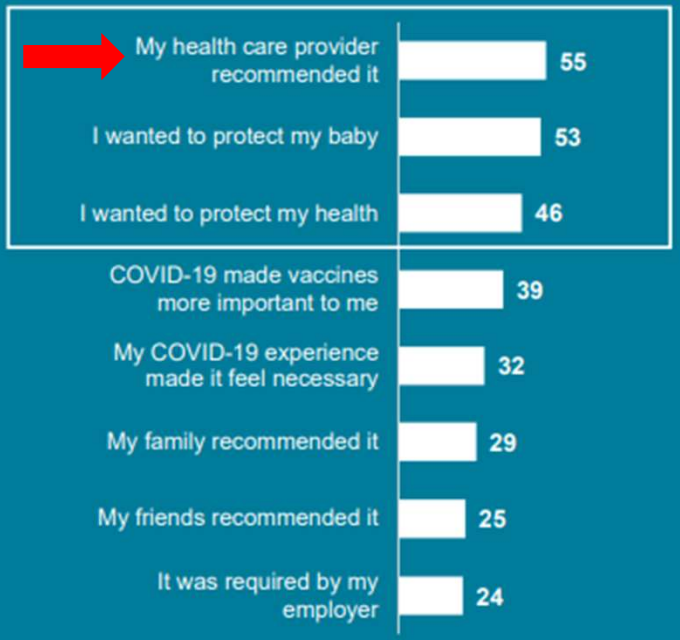
Top Reasons for Getting Tdap Vaccine
(Percent Ranked Top 3)
Sub-sample who received Tdap vaccine before or during pregnancy



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



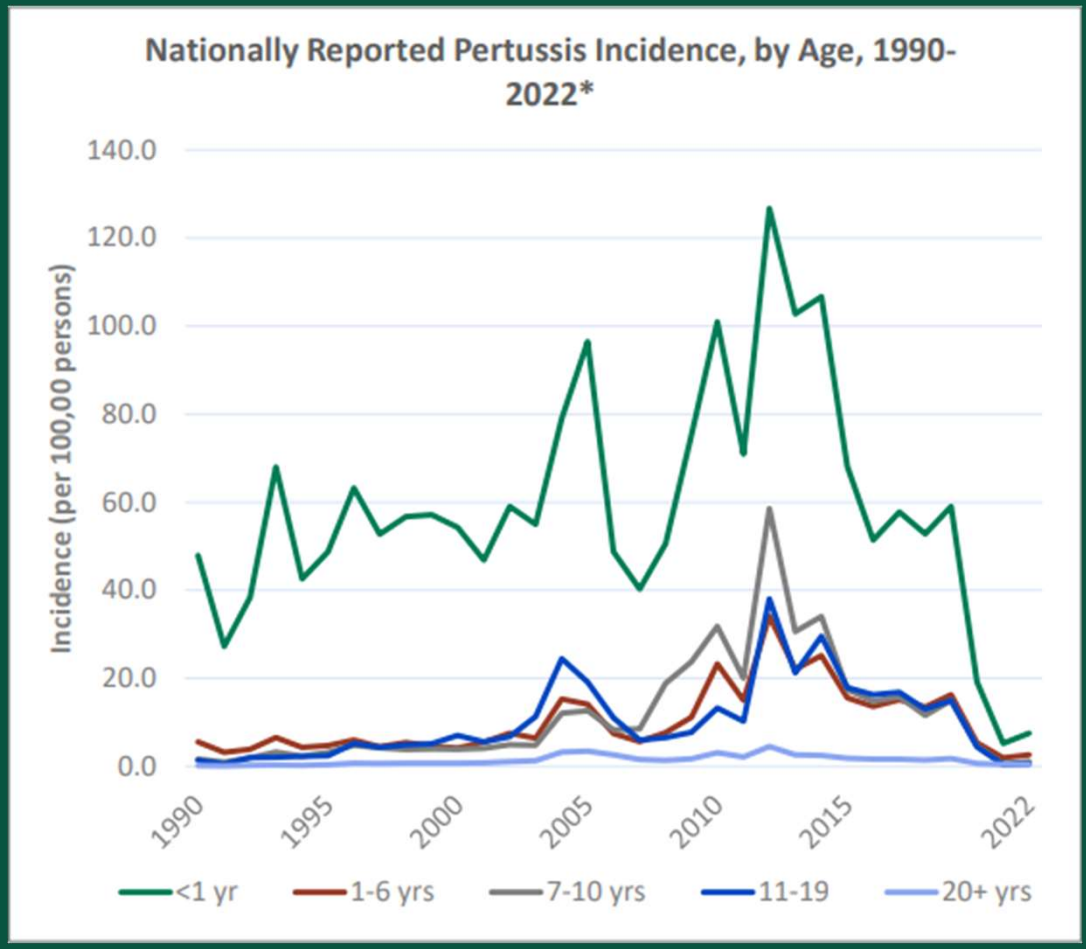
Knowledge Check!

Which of the following is the most commonly cited **obstacle** for COVID, flu and pertussis vaccination during pregnancy?

A. Cost
B. Time
C. Vaccine Safety
D. None of the Above

Tdap vaccines during pregnancy: protection for mothers and infants

Whooping cough is poorly controlled in the U.S., despite high vaccine coverage



CDC, 2024; Jatlaoui & Joseph, COCA Call, Aug 10, 2023

A call to action:

NORTH Dakota | Health & Human Services
Be Legendary.

Call to Action: Prenatal Care Providers Urged to Vaccinate All Pregnant Patients Against Pertussis. North Dakota infants have become severely ill from pertussis, and you can make a difference.

North Dakota is experiencing increased circulation of pertussis, and our smallest citizens are bearing the greatest cost. Since August of 2023, 124 cases of pertussis have been identified in North Dakota. Eight individuals have been hospitalized, and seven of these have been infants younger than 12 months. Babies are extremely vulnerable to pertussis, often requiring mechanical ventilation, and sometimes resulting in death.

Health care providers can have a major impact on preventing these cases by **vaccinating expectant patients during every pregnancy**. Tdap (tetanus, diphtheria, and acellular pertussis vaccine) should be administered between 27 to 36 weeks gestation to protect the newborn during the highest risk months of life. Tdap vaccination during pregnancy prevents about **78%** of pertussis cases and about **90%** of hospitalizations in infants younger than two months. According to an analysis, only 60.6% of babies born in North Dakota during 2018 had mothers who had received Tdap vaccine during pregnancy.

Since August 2023:

124
Cases of pertussis

8
hospitalized
7 of these among infants <12 months

in *North Dakota*

Among infants who get pertussis:

1/2

End up in the hospital

1 in 5

Infants hospitalized for pertussis will get pneumonia

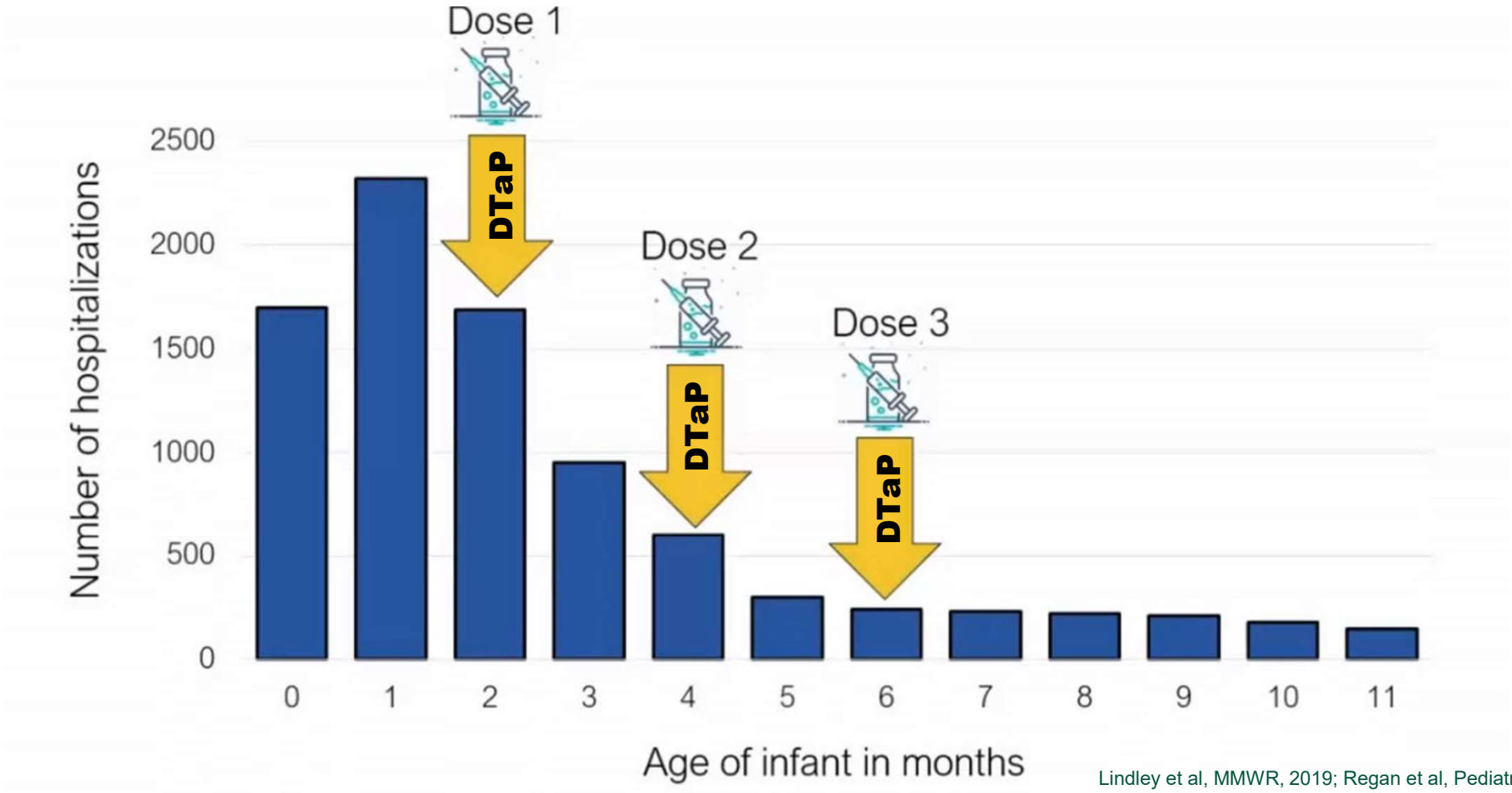
1 in 100

infants hospitalized for pertussis will die

Most deaths are among infants who are too young to be protected by childhood vaccination.

CDC, 2024; Jatlaoui & Joseph, COCA Call, Aug 10, 2023

Number of infants with pertussis who were hospitalized, by age in months (N = 7,731) — National Notifiable Diseases Surveillance System, United States, 2010–2017



Lindley et al, MMWR, 2019; Regan et al, Pediatrics, 2023

2011

Tdap vaccination recommended during pregnancy for previously unvaccinated women.

2012

Tdap vaccination recommendation expanded to include every pregnant woman during each pregnancy.

CDC recommends all women receive Tdap between the 27th and 36th week of each pregnancy

CDC, 2024; Moro et al, Hum Vaccin Immunother, 2015; Jatlaoui & Joseph, COCA Call, Aug 10, 2023

CDC, 2024; Jatlaoui & Joseph, COCA Call, Aug 10, 2023

Knowledge Check!

True or False: Young infants account for a ***minority*** of all pertussis-attributable hospitalizations and deaths in the United States.

A. True
B. False

SARS-CoV-2 infection and COVID-19 vaccination in pregnant women

The impact of COVID-19 infection:

Pregnant and recently pregnant people have a

2.5X

higher odds of ICU admission from COVID vs non-pregnant women.

75%

of babies hospitalized with COVID-19 were born to women who did not receive the COVID vaccine.

Jatlaoui & Joseph, COCA Call, Aug 2023;CDC, 2024

Recent reports have shown that breastfeeding people who have received mRNA COVID-19 vaccines have SARS-CoV-2 antibodies in their breast milk, which could help protect their babies.

CDC, 2024; Hunagund et al, Frontiers in Immunology, 2022

Everyone ages 6 months and older is recommended to get the updated COVID-19 vaccine, including people who are pregnant, breastfeeding a baby, trying to get pregnant now, or who might become pregnant in the future.

CDC recommendation aligns with those from:

ACOG

Society for Maternal-Fetal Medicine

asrm
American Society for Reproductive Medicine

COVID-19 vaccination is *safe* in pregnancy*

Studies including hundreds of thousands of people around the world show that COVID-19 vaccination during pregnancy is safe, effective, and beneficial to both mom and baby.

Studies show

No Increased Risk

of complications like miscarriage, preterm delivery, stillbirth, or birth defects.

*Data represented on this slide represents findings on mRNA COVID-19 vaccines. Emerging post-introduction pharmacovigilance data relating to the use of NVX-CoV2373 (Novavax COVID-19 vaccine) in pregnant women have not identified any pregnancy-related safety concerns and based on previous evidence from other protein-based vaccines during pregnancy, efficacy is expected to be comparable to non-pregnant women of a similar age.

Marchand et al, Nature, 2023; CDC, 2024; Jatlaoui & Joseph, COCA Call, Aug 2023; WHO, 2024

Neonatal Outcomes After COVID-19 Vaccination in Pregnancy

JAMA | Original Investigation

Neonatal Outcomes After COVID-19 Vaccination in Pregnancy

Mikael Norman, MD, PhD; Maria C. Magnus, PhD; Jonas Söderling, PhD; Petur B. Juliusson, MD, PhD; Lars Navér, MD, PhD; Anne K. Örtqvist, MD, PhD; Siri Håberg, MD, PhD; Olof Stephansson, MD, PhD

CONCLUSIONS AND RELEVANCE In this large population-based study, vaccination of pregnant individuals with mRNA COVID-19 vaccines was not associated with increased risks of neonatal adverse events in their infants.

Population-based cohort study from Sweden and Norway looking at almost 200,000 infants showed that maternal receipt of the COVID-19 vaccine during pregnancy poses no risk to infants, and instead prevents babies from suffering serious complications.

Norman et al, JAMA, 2024

Compared to unvaccinated pregnant people, those who received a bivalent COVID-19 vaccine had an estimated:

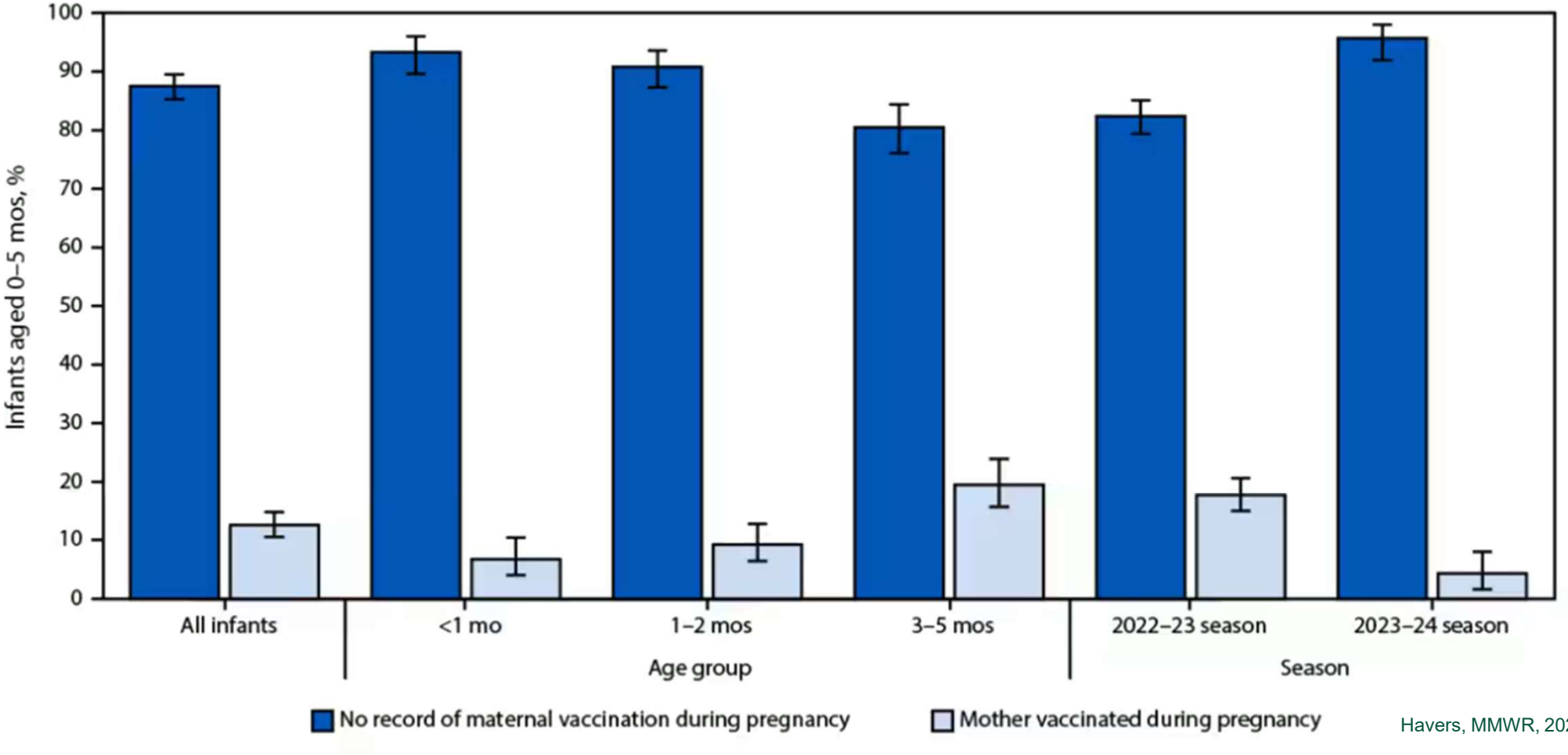
61%
Reduced risk of emergency department/ urgent care visits in pregnant women

56%
Reduced risk of hospitalization in infants <3 months

38%
Reduced risk of hospitalization in infants <6 months

Marchand et al, Nature, 2023; CDC, 2024; Jatlaoui & Joseph, COCA Call, Aug 2023

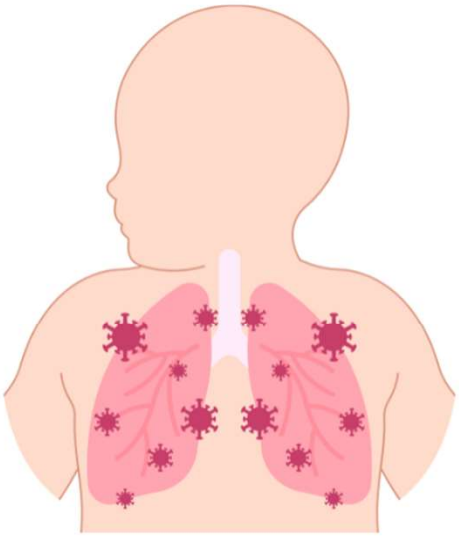
Maternal vaccination status among infants aged <6 months hospitalized with laboratory-confirmed SARS-CoV-2 infection, by age group and season — COVID-19–Associated Hospitalization Surveillance Network, 12 states, October 2022–April 2024

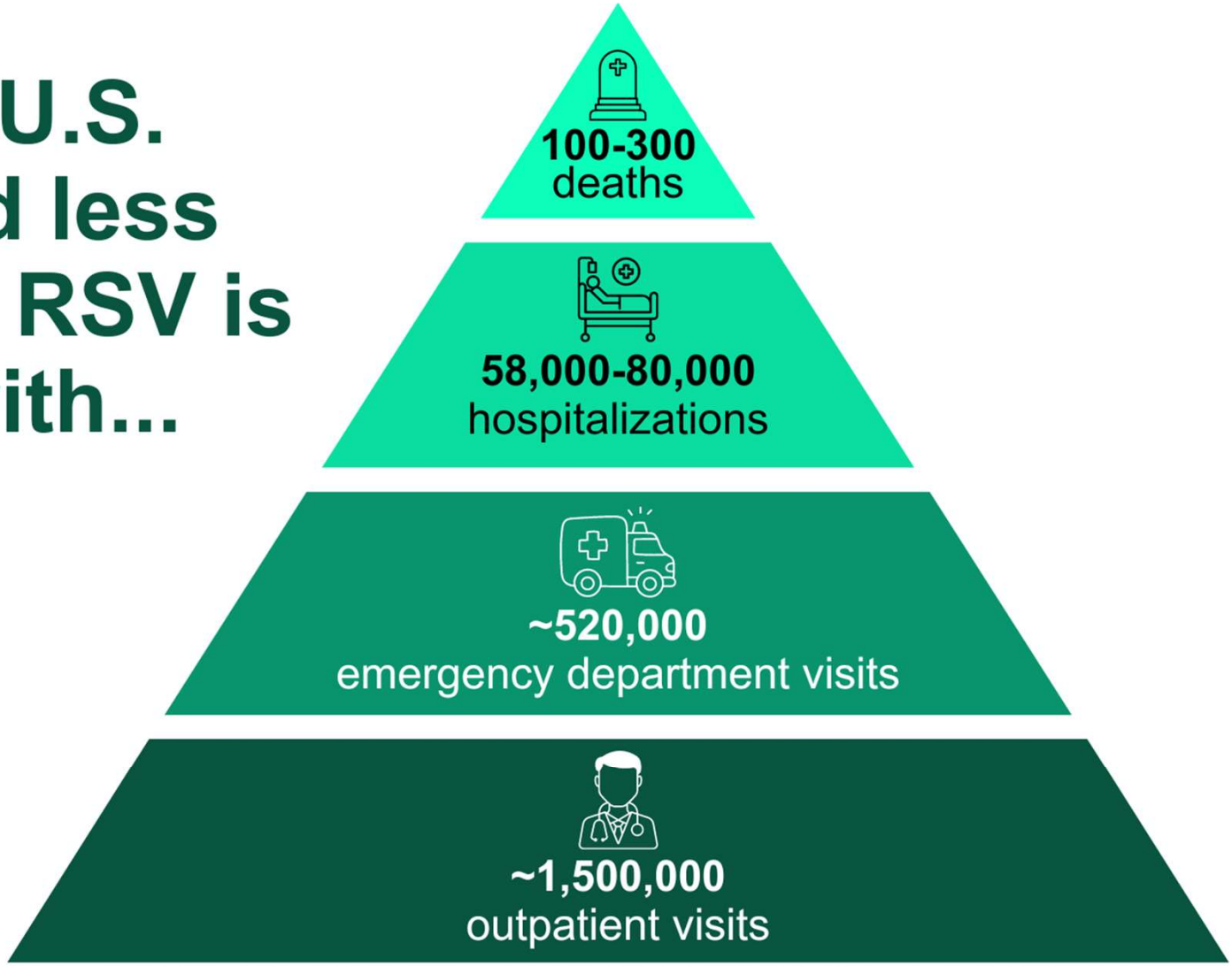


Havers, MMWR, 2024

RSV infection and RSV immunizations to help protect infants

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





Thompson et al, JAMA, 2003; Hansen et al, JAMA Network Open, 2022; Hall et al, NEJM, 2009; McLaughlin et al, J Infect Dis, 2022
(* Estimate 80,000 hospitalization in infants <1 yrs)

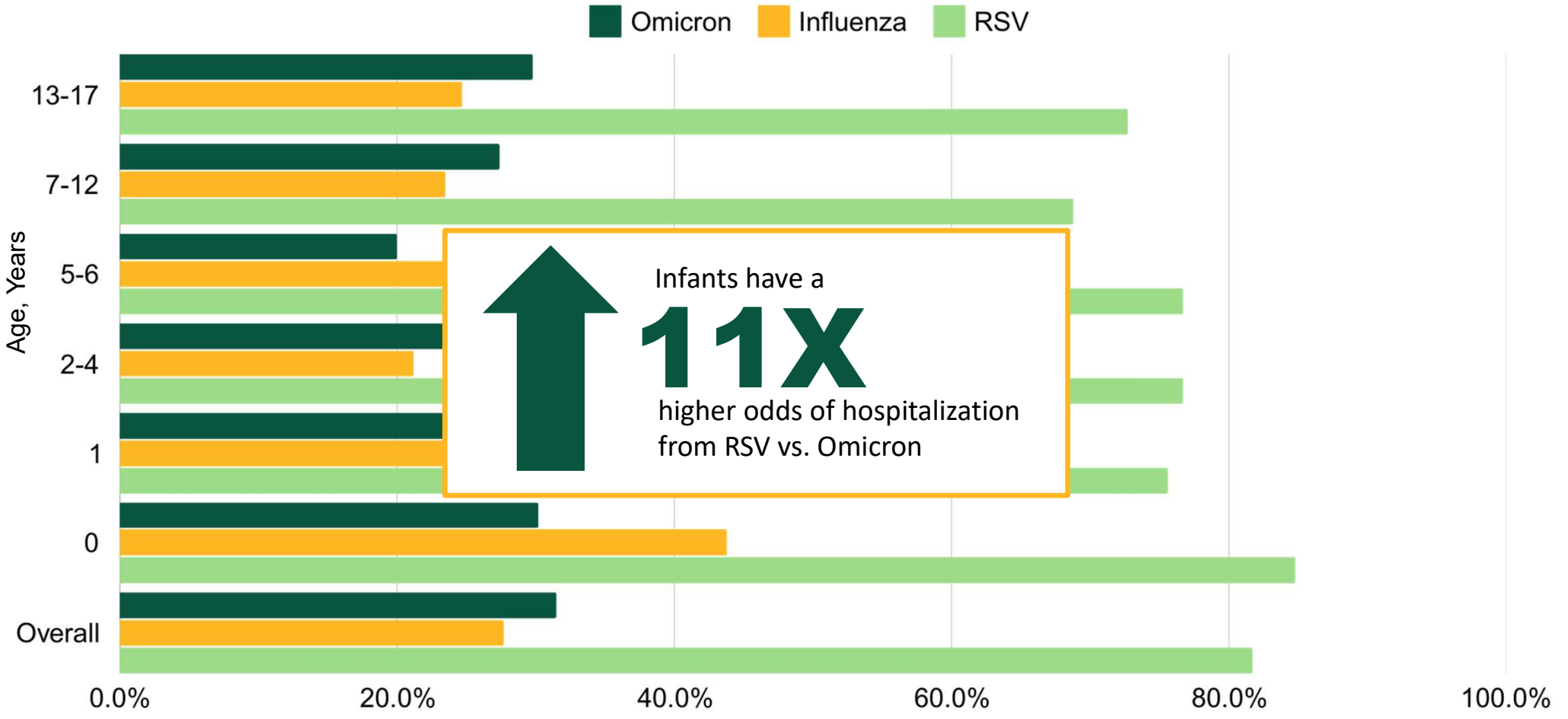
RSV is the #1 cause of hospitalization among U.S. infants

79%

of children <2 years old hospitalized with RSV have NO underlying medical conditions

Jones et al, MMWR, 2023

Age-Stratified Hospital Admission Rates in Cohorts With SARS-CoV-2 Omicron, Influenza A/B, or RSV Infection



Hedberg et al, JAMA, 2023

CDC recommends the use of one of two tools to protect infants from getting very sick with RSV:

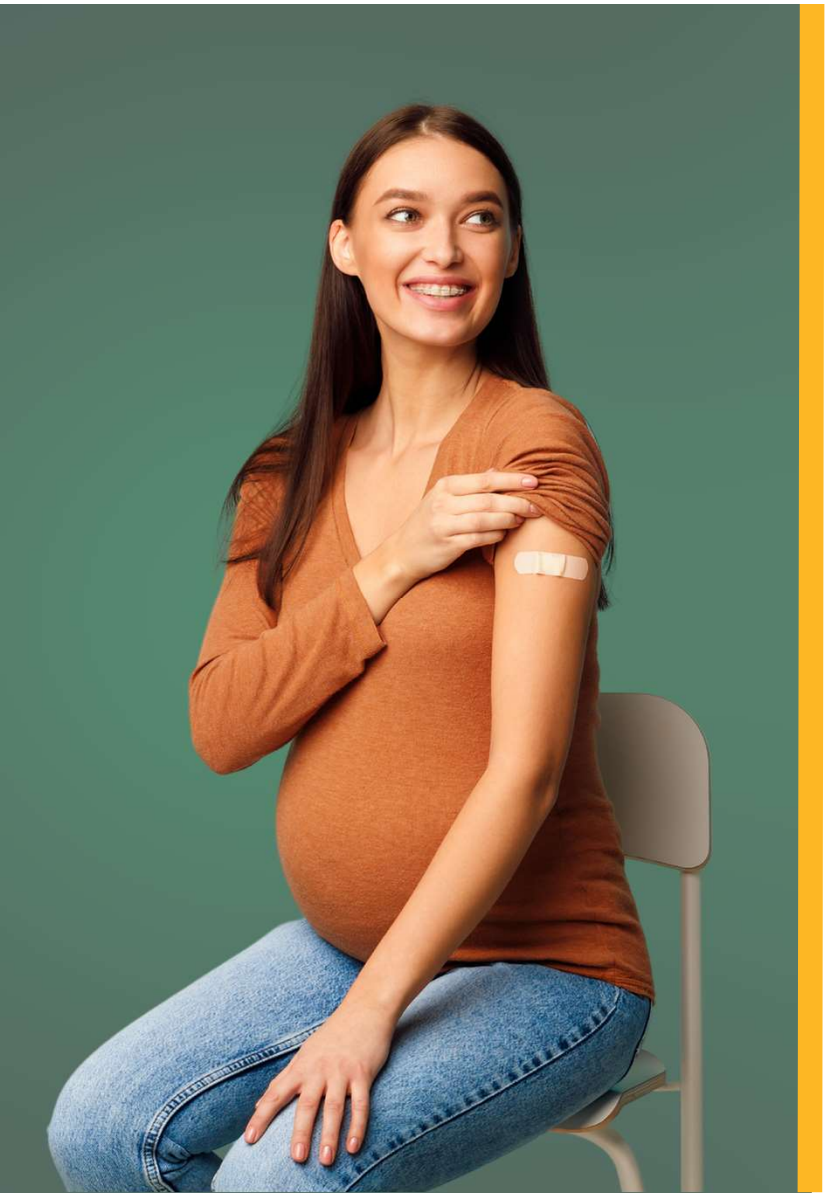
1. An RSV vaccine given during pregnancy

OR

2. An RSV immunization given to infants or older babies

Most infants will not need both.

CDC, 2024



Maternal RSV Vaccine

Abrysvo: 1st RSV vaccine for pregnancy to prevent RSV in infants birth – 6 months

FDA approved for use at 32 – 36 weeks gestation

Safety and effectiveness evaluation ongoing in randomized, placebo-controlled international clinic trials

Preliminary data shows:

- ↓ **81.8%** Reduced risk of severe LRTD within 90 days of birth
- ↓ **69.4%** Reduced risk of severe LRTD within 180 days of birth

CDC, 2024; FDA, 2024

Infant RSV Immunization

Nirsevimab: All infants <8 months of age born during RSV season or entering their first RSV season; AND children 8-19 months at increased risk of severe RSV entering their second RSV season.

Except in rare circumstances, most infants <8 months of age do not need nirsevimab if they were born 14+ days after their mother got an RSV vaccine.

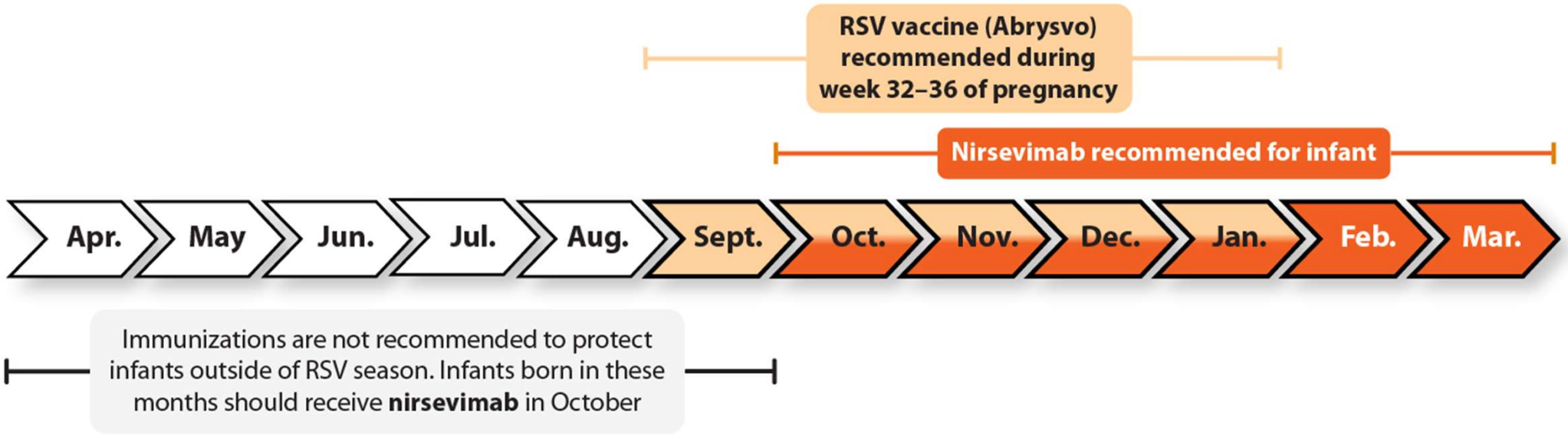
In clinical trials, the RSV vaccines and passive immunization (monoclonal antibody product) were shown to be safe and effective at preventing RSV-associated lower respiratory tract disease (LRTD).

1st season effectiveness: Oct 2023 - March 2024

- ↓ **89%** Medically attended RSV-associated acute respiratory illness
- ↓ **91%** RSV-associated hospitalization

Moline, MMWR, 2024; Payne, ACIP, June 28, 2024; CDC, 2024

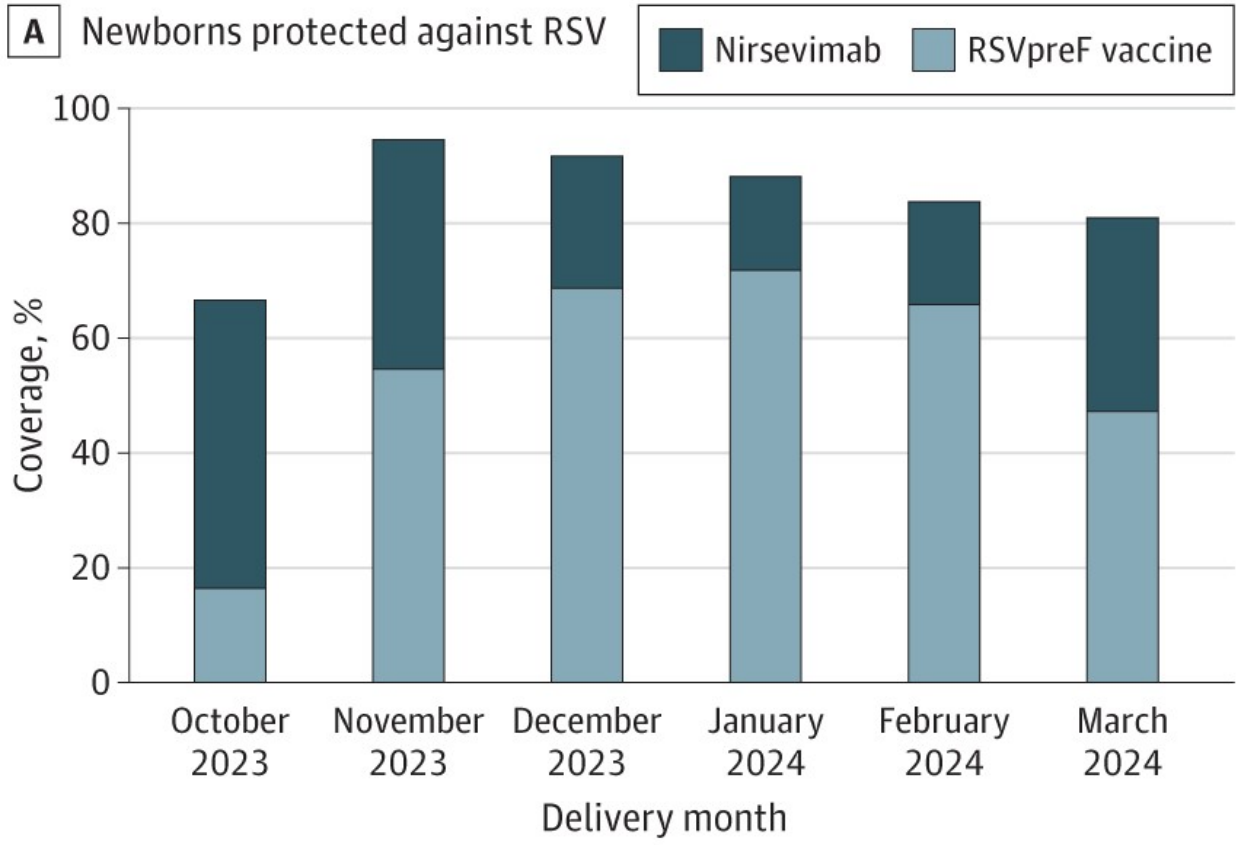
Seasonal Recommendations

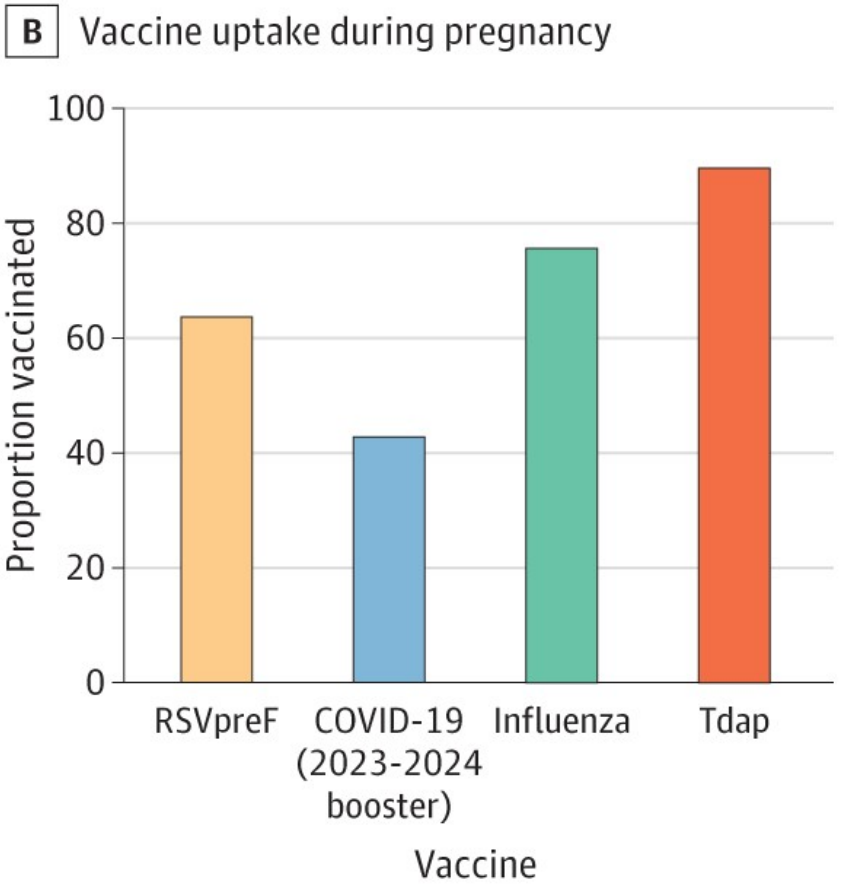


RSV typically peaks between December and February. It is important that babies have protection before RSV season peaks.

CDC, 2024

Uptake of Prenatal Vaccines and Infant Nirsevimab

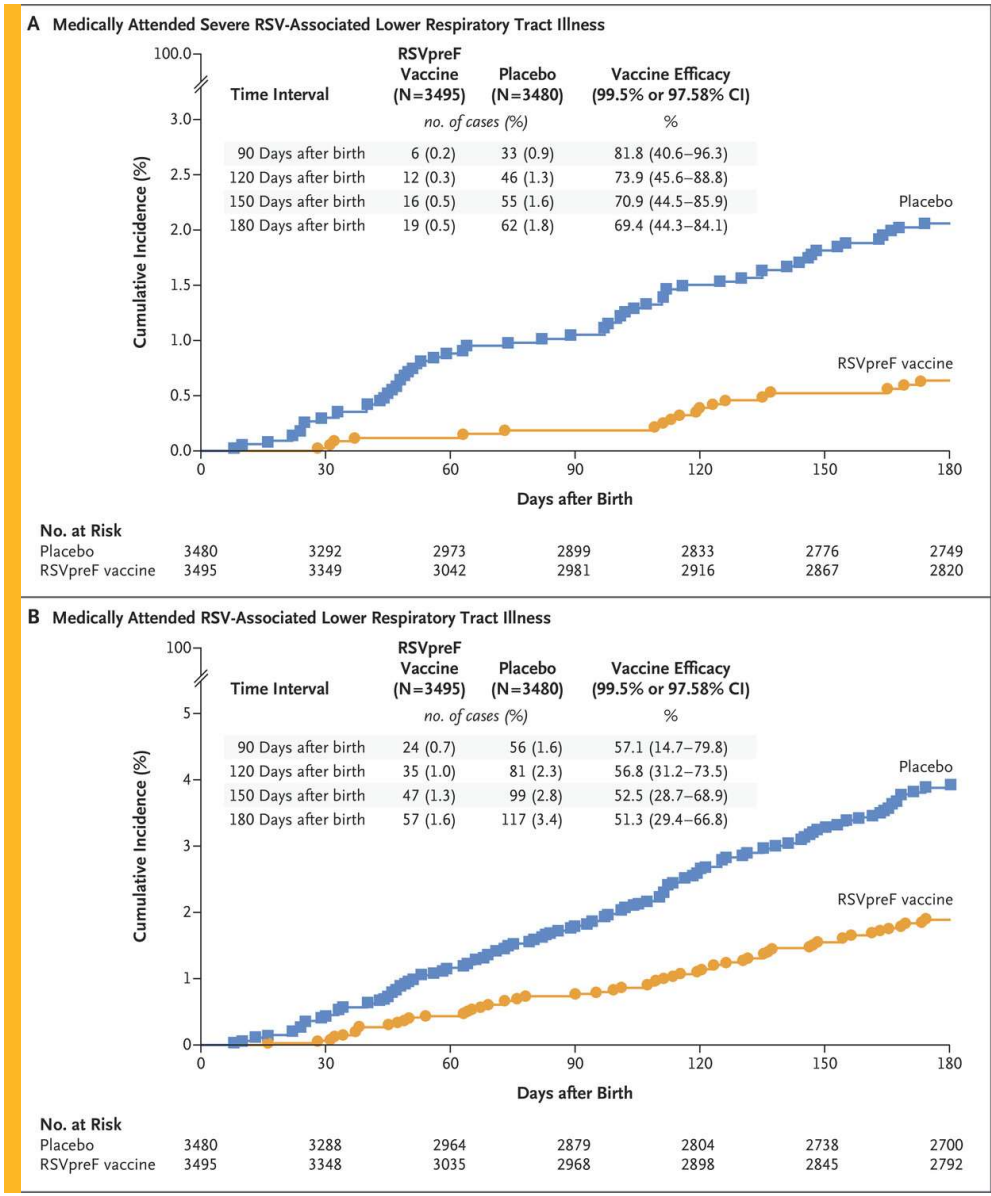




Blauvelt et al, JAMA, 2025

Maternal RSV Vaccine Efficacy

- In the first 3 months, maternal RSV vaccine reduced the risk of infant hospitalization for RSV by 68% and having a healthcare visit for RSV by 57%
- In the first 6 months, maternal RSV vaccine reduced the risk of infant hospitalization for RSV by 57% and having a healthcare visit for RSV by 51%



Kampmann et al, NEJM, 2023

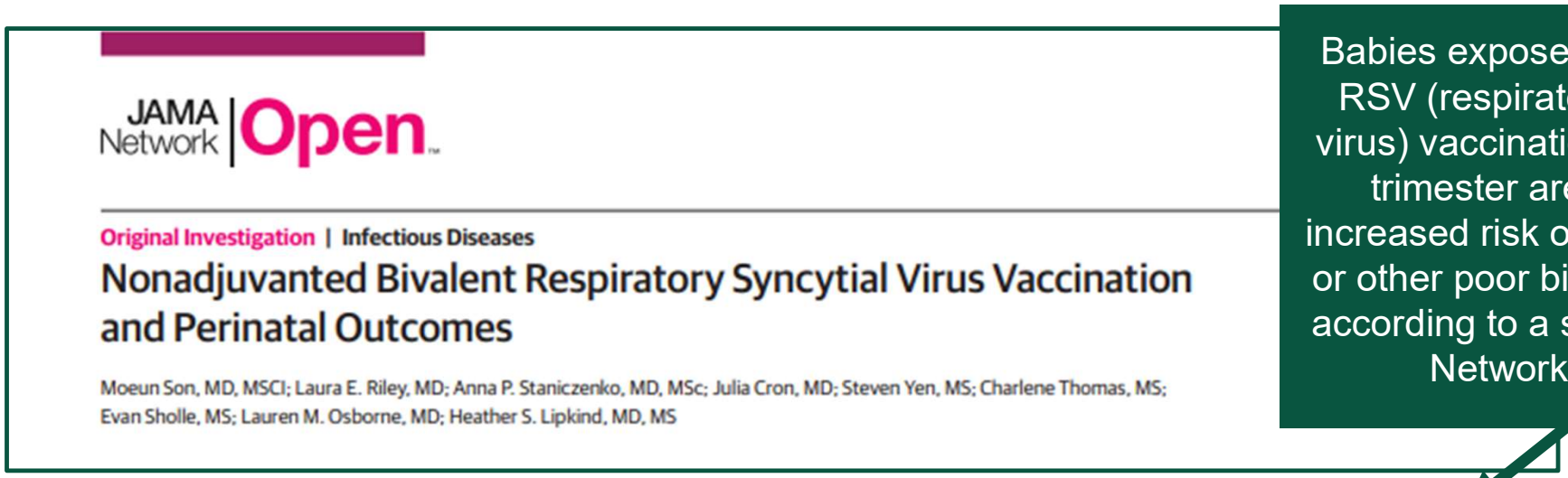
Maternal RSV Vaccine Safety

- Most common side effects: pain at injection site, headache, myalgia, nausea

- Preterm birth
  - Pre-licensure trial initially included pregnant persons at weeks 24-36 gestation
  - More preterm births were seen in vaccine recipients vs. placebo (not statistically significant)
  - In pregnant women 32-36 weeks gestation who received vaccine, 4.2% had preterm birth compared to 3.7% placebo
  - ***Available data were insufficient to establish or exclude causal relationship***

CDC, 2024

Late-pregnancy RSV vaccination not associated with poor birth outcomes



JAMA Network | Open

Original Investigation | Infectious Diseases

Nonadjuvanted Bivalent Respiratory Syncytial Virus Vaccination and Perinatal Outcomes

Moeun Son, MD, MSCI; Laura E. Riley, MD; Anna P. Staniczenko, MD, MSc; Julia Cron, MD; Steven Yen, MS; Charlene Thomas, MS; Evan Sholle, MS; Lauren M. Osborne, MD; Heather S. Lipkind, MD, MS

Babies exposed to maternal RSV (respiratory syncytial virus) vaccination in the third trimester are not at an increased risk of preterm birth or other poor birth outcomes, according to a study in JAMA Network Open.

CONCLUSIONS AND RELEVANCE In this cohort study of pregnant individuals who delivered at 32 weeks' gestation or later, the RSVpreF vaccine was not associated with an increased risk of PTB and perinatal outcomes. These data support the safety of prenatal RSVpreF vaccination, but further investigation into the risk of HDP is warranted.

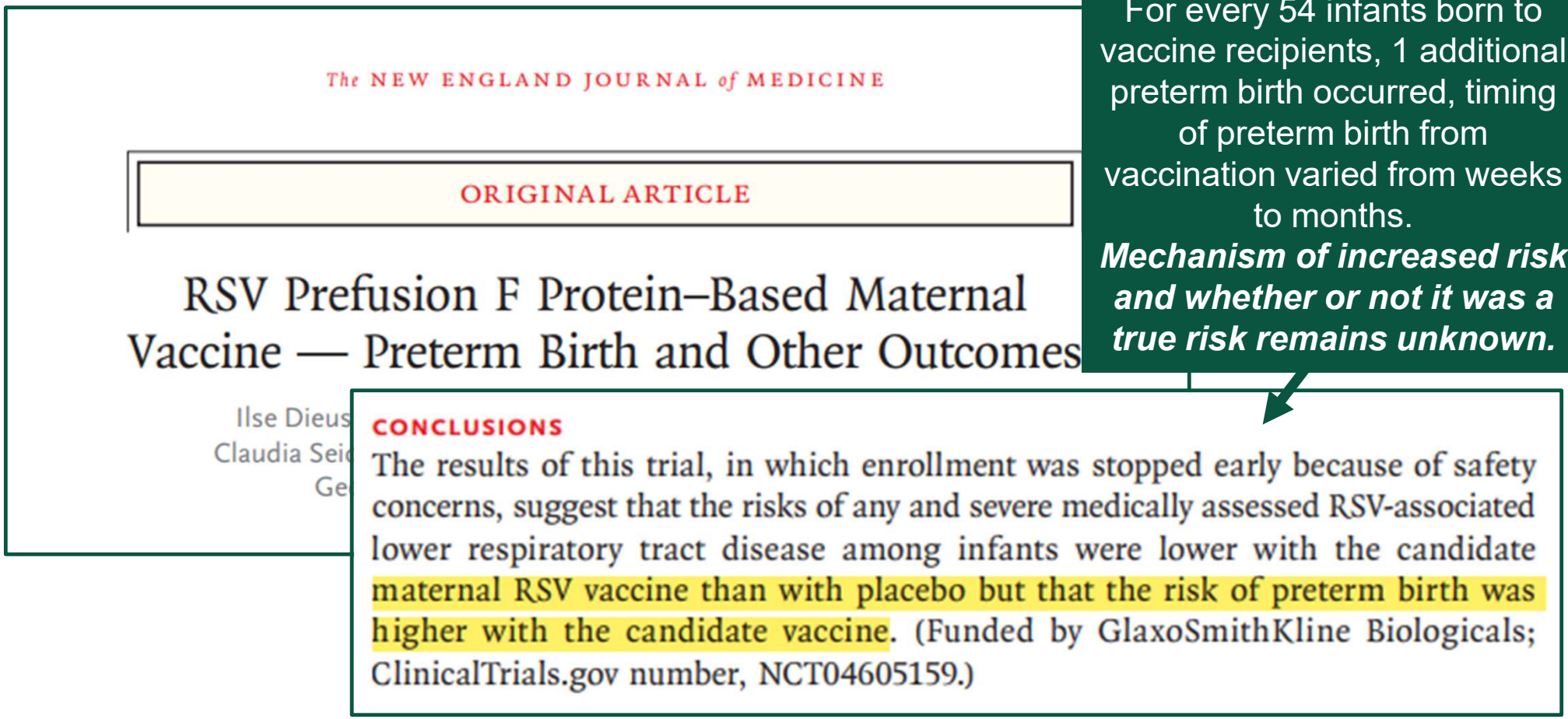
Son et al, JAMA, 2024

GSK halts prenatal RSV vaccine trial

- Preterm births in vaccine group > than placebo (6.8% vs 4.9%)
- Of preterm births, 5.5% in vaccine group were very (<32 weeks) or extremely (<28 weeks) preterm vs. 2.3% in placebo group
- Neonatal death risk higher in vaccine group (due to extreme prematurity)

Dieussaert et al, NEJM, 2024

Follow up on GSK Clinical Trial



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

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

Ilse Dieus
Claudia Seid
Ge

CONCLUSIONS

The results of this trial, in which enrollment was stopped early because of safety concerns, suggest that the risks of any and severe medically assessed RSV-associated lower respiratory tract disease among infants were lower with the candidate maternal RSV vaccine than with placebo but that the risk of preterm birth was higher with the candidate vaccine. (Funded by GlaxoSmithKline Biologicals; ClinicalTrials.gov number, NCT04605159.)

For every 54 infants born to vaccine recipients, 1 additional preterm birth occurred, timing of preterm birth from vaccination varied from weeks to months.

Mechanism of increased risk and whether or not it was a true risk remains unknown.

Dieussaert et al, NEJM, 2024

Other Vaccine Safety Outcomes

- Overall uncommon, but hypertensive disorders of pregnancy occurred in 1.8% of maternal vaccine recipients vs 1.4% placebo
- The following conditions (often associated with preterm birth) occurred more frequently in infants born to mothers who received the RSV vaccine compared to placebo:
  - Pre-eclampsia
  - Low birth weight (< 5.5 lbs)
  - Jaundice

CDC, 2024

Small for Gestational Age (SGA) at birth risk in infants born to RSV vaccinated pregnant person or unvaccinated pregnant matches, 30-36 weeks gestational age

	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)

SGA - birthweight <10th percentile for gestational age compared with a U.S. reference population
*Events only included through date of censoring when unvaccinated pair corsses over to vaccinated

RSVpreF vaccine is not associated with increased risk for preterm birth or SGA at birth.

DeSilva, ACIP Presentation, Oct 23, 2024

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)

RCT = randomized clinical trial | ARI = acute respiratory illness

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

Jones et al, MMWR, 2024

Infant who received nirsevimab in the 2023-24 season:

~76%

less likely to visit a health care provider because of RSV.

70 - 90%

less likely to be hospitalized with RSV.

80%

less likely to be admitted to the PICU for RSV.

Moline, et al. MMWR, 2024; Lopez-Lacort, et al. Eurosurveillance, 2024; Assad, et al. *NEJM*, 2024; Lopez-Lacort, et al. *Pediatrics*, 2024; Payne, Presentation at ACIP 6/28/2024

	Advantages	Disadvantages
Maternal RSV Vaccine 	• Immediate protection for baby after birth • Reduces number of vaccines for infant at birth	• Potentially reduced protection in some situations (e.g., pregnant person is immunocompromised or infant born soon after vaccination) • Potential risk for hypertensive disorders of pregnancy (recent data are reassuring)
Nirsevimab 	• Protection may wane more slowly than from maternal RSV vaccine • Direct receipt of antibodies rather than relying on transplacental transfer • No risk for adverse pregnancy outcomes	• Requires infant injection • Delay in administration could leave the infant unprotected

ACOG, 2024

Should a pregnant person receive maternal RSV vaccine during pregnancy this season if they received maternal RSV vaccine during pregnancy in a previous season?

No.

Rather, that infant should receive nirsevimab.

ACOG, 2024

Flu in pregnancy and vaccines that prevent it

Pregnant women are at increased risk of:

Pregnancy loss and reduced birthweight,
Preterm labor and birth,
Severe illness,
Hospitalization,
and Death

from the flu.

CDC, 2024; Dawood et al, The Lancet, 2021; Lindley et al, MMWR, 2019; Sahni et al, JAMA, 2023

Infants aged <6 months have the highest risk for hospitalization with influenza of all children and are too young to get influenza vaccines.

CDC, 2024; Jatlaoui & Joseph, COCA Call, Aug 2023; Bryant & Uyeki, COCA Call, Nov 2024

Women who get the flu vaccine while pregnant or breastfeeding develop antibodies against flu that they can share with their infants through their breast milk.

Breastfeeding can provide some protection against flu for infants, including children <6 months who cannot receive the flu vaccine.

CDC, 2024

Recommendations for pregnant persons

- Flu vaccines may be given during any trimester of pregnancy
- Flu vaccines ideally should be offered in Sept. or Oct. (with continued vaccination throughout the flu season)
- Early vaccination can be considered (July-Aug.) for pregnant persons in their 3rd trimester to optimize protection for their infant

Jatlaoui & Joseph, COCA Call, Aug 2023

Flu vaccination is *safe* in pregnancy:

Flu vaccines have been given to

Millions

of pregnant women over *several decades* and are *safe.*

There is lots of evidence to show that flu shots are safe and both the

CDC & ACOG

recommend that pregnant women get vaccinated.

CDC, 2024; ACOG, 2024

Flu vaccination is *effective* in pregnancy and can lead to:

50%
Reduced risk of flu-associated acute respiratory infection in pregnant women

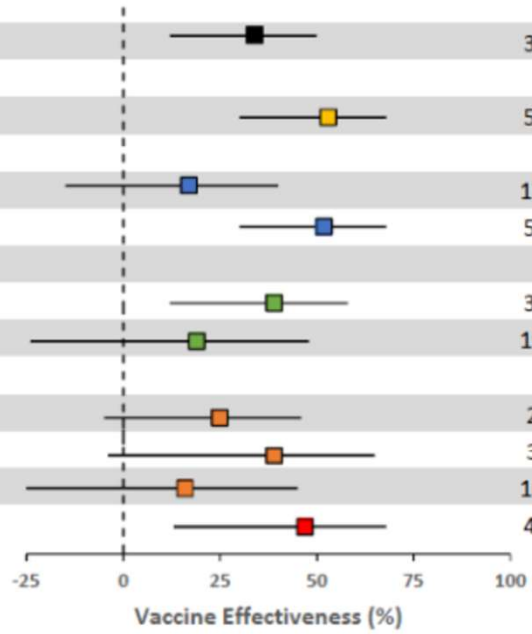
40%
Reduced risk of hospitalization in pregnant women

72%
Reduced risk of hospitalization in infants <6 months

Jatlaoui & Joseph, COCA Call, 2023; CDC, 2024; Nunes & Madhi, Hum Vaccin Immunother, 2018; Thompson et al, Clin Infect Dis, 2019

Maternal Vaccine Effectiveness against Influenza-associated Hospitalization and Emergency Department Visits in Infants <6 months

Infants <6 months of age	No. Vaccinated Mothers /Total no. (%)		Effectiveness of Maternal Vaccination against Influenza Illness in Infants % (95% CI)
	Case-infants	Control-infants	
Overall effectiveness of maternal vaccination	94/223 (42)	1913/3541 (54)	34 (12 to 50)
Infants <3 months of age	49/106 (46)	1293/2147 (60)	53 (30 to 68)
Vaccinated during first or second trimester of pregnancy	59/188 (31)	1009/2637 (38)	17 (-15 to 40)
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)

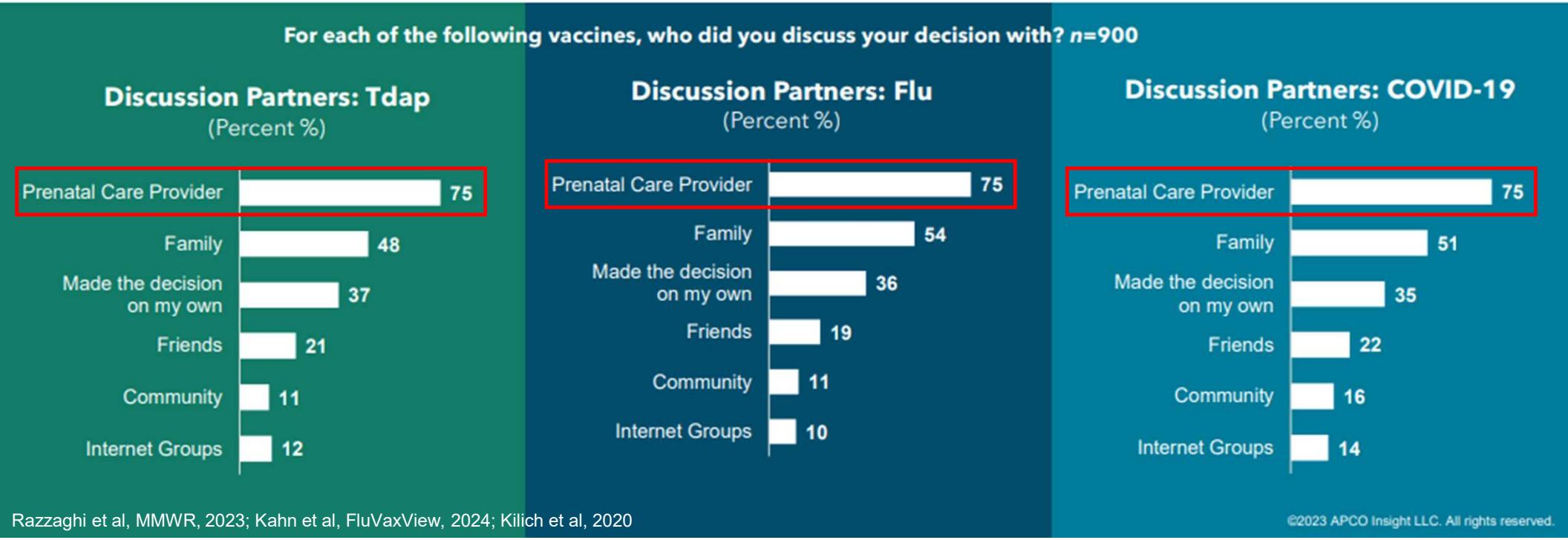


Olson, ACIP Meeting, Oct 25, 2023

Communication tools to improve your vaccine conversations.

Prenatal care providers emerge as the most trusted source for vaccine information

75% of respondents stated their prenatal care provider was the most important source of vaccine information

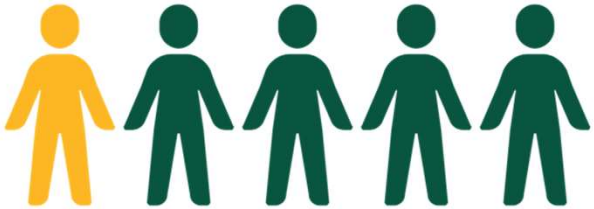


Razzaghi et al, MMWR, 2023; Kahn et al, FluVaxView, 2024; Kilich et al, 2020

Lack of provider recommendations

During the 23-24 flu season, a number of pregnant women indicated they *did not receive* a provider recommendation for vaccination:

1 in 4 for flu vaccine



1 in 5 for Tdap vaccine

2 in 5 for updated COVID vaccine

REMINDER: ***Vaccination coverage is highest among pregnant women with a provider offer or referral for vaccination.***

Kahn et al, FluVaxView, 2024

Addressing vaccine hesitancy: One size does not fit all

Communication Strategies by Motivation to Act and Level of Resistance

Presumption

Motivational Interviewing & Empathy

High Motivation to Act
Low Resistance

Some Motivation to Act
Some Resistance

Low Motivation to Act
High Resistance

Presumption of Vaccination

Strong provider recommendations are correlated with increased vaccine acceptance versus participatory communication.

"I strongly recommend we protect you and baby today by getting you vaccinated against flu and COVID-19."	V S	"Are we doing shots today?"
Presumptive		**Participatory**

Provider recommendation is the factor most strongly associated with vaccination among pregnant people.

William et al, Pediatrics, 2020; Nowak, Int J Environ Res Public Health , 2018; Gilkey et al, Vaccine, 2016; Brewer et al, Pediatrics, 2017; CDC, 2023; Kilich et al, 2020

Advantages of the Presumptive Method

It works!

Presumptive approach improves vaccine acceptance.

Similar approach to making other medical recommendations

The more confident you are, the more confident the patient is likely to be.

Saves time

Most patients and families are highly accepting of vaccines.

Based upon the information we just covered, is this a 👎 or a 👍?

As a part of your prenatal care, you can get a Tdap vaccine. What would you like to do today?

Based upon the information we just covered, is this a 👎 or a 👍?

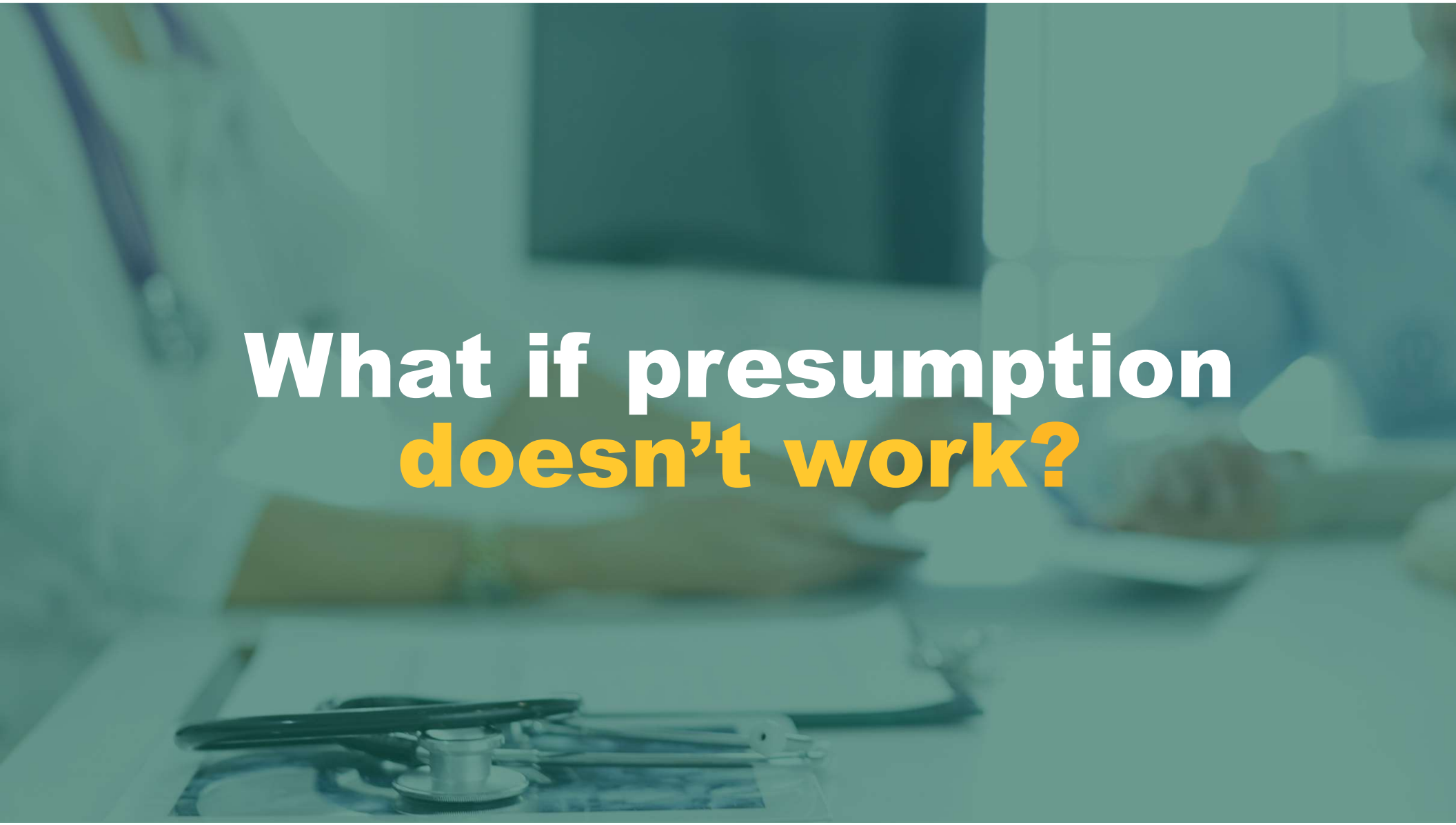
As a part of your prenatal care, you can get a Tdap vaccine. What would you like to do today?

Hmm, you know I think we will skip that today. One less thing I have to do!

Based upon the information we just covered, is this a 👎 or a 👍?

As part of your prenatal care, I strongly recommend a Tdap vaccination today. I recommend this to all my patients around 28 weeks to provide baby with the best protection against whooping cough in their first few months of life. Do you have any questions?

No, that sounds good!


What if presumption
doesn’t work?

Analyzing Strategies by Motivation to Act and Level of Resistance

Presumption

Motivational Interviewing & Empathy

High Motivation to Act
Low Resistance

Some Motivation to Act
Some Resistance

Low Motivation to Act
High Resistance

MI Communication Techniques

Open Ended Questions *"You aren't sure about the flu vaccine today. What worries you?"*	**Reflect Back** *"You are really worried about the ingredients in vaccines."*	**Honor Ambivalence** *"So, you don't want baby to be at risk from pertussis, but you are also worried about how safe vaccines are in pregnancy. Many patients feel that way."*
Ask Permission to Share *"Can I share some information that I think might ease your mind?"*	**Make a Strong Recommendation** *"During my own pregnancy I received a Tdap vaccine, and I recommend it to all of my patients."*	**Support Autonomy** *"It is your body, and this is your decision."*

SCALING QUESTIONS

"On a scale of 0 to 10, how important is it for you to get the vaccine today?"

- "Why did you say 5 and not a lower number, like 3?"
- "What would it take to get you to a higher number, like 6 or7?"

CASE STUDY

Great to see you, Julie! I see you are here for your 28-week appointment. As a part of today's visit, I strongly recommend Tdap and flu vaccines to ensure both you and your baby stay healthy. Do you have any questions?

You know, I am really uncertain about getting vaccinated during pregnancy. One of the influencers I follow on Instagram shared how unsafe vaccinating in pregnancy can be for the baby. Specifically, it can cause early delivery and possibly even stillbirth! I know she isn't an expert, but the things she shared scared me.

You aren't the first patient that has come to me with this concern. Can I share some information with you?

Sure.

CASE STUDY #1: The Facts!

Tdap and flu vaccines are safe for a pregnant person and their baby

- The Tdap and the flu vaccines recommended in pregnancy are inactivated vaccines. ***They are NOT live virus vaccines***, such as the MMR and chickenpox vaccines, which should not be given to pregnant people.
- Tdap and flu vaccines have been given to millions of people over many years with an excellent safety record.
- There is a large body of scientific studies that supports the safety of these vaccines in pregnant people and their babies, and we continue to gather data on this topic.
- Concomitant administration of indicated inactivated vaccines during pregnancy (i.e., Tdap and flu vaccines given in same visit) is also acceptable, safe, and may optimize effectiveness of immunization efforts.

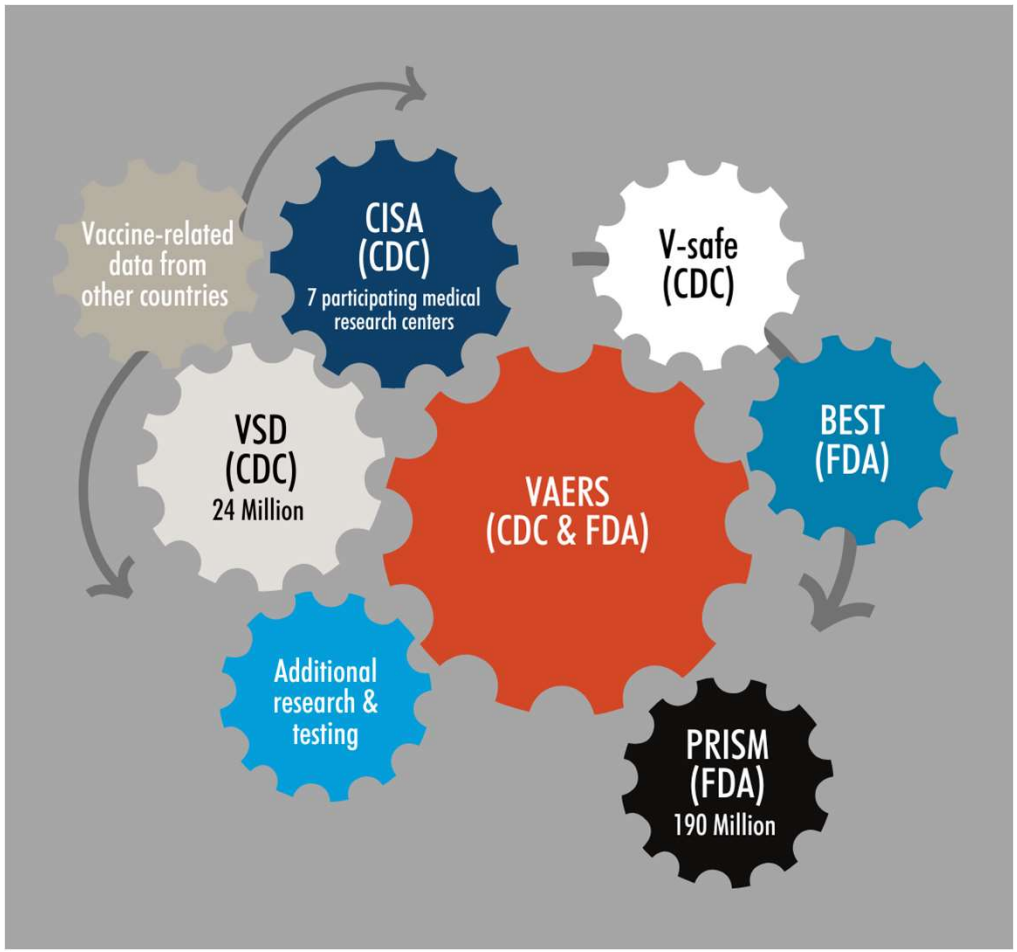
Acknowledge common side effects of vaccination.

- Pain, redness, or swelling in the arm where the shot was given are common.
- Side effects are generally self-limiting. Put into perspective: Vaccination in pregnancy is the *best protection for mom and baby in the first few months of life.*

ACOG, 2024

How is the safety of vaccines in pregnant people monitored?

- Ongoing safety monitoring:
  - Vaccine Adverse Event Reporting System (VAERS)
  - Vaccine Safety Datalink (VSD)
  - V-safe



CDC, 2024; NDHHS/CIRE Vaccine Safety Handout, 2024

Safety of coadministration of Tdap and flu vaccine in pregnancy

Published in final edited form as:

Obstet Gynecol. 2015 November ; 126(5): 1069–1074. doi:10.1097/AOG.0000000000001066.

Safety of Tetanus, Diphtheria, and Acellular Pertussis and Influenza Vaccinations in Pregnancy

Conclusion—Concomitant administration of Tdap and influenza vaccines during pregnancy was not associated with a higher risk of medically attended adverse acute outcomes or birth outcomes compared to sequential vaccination.

CASE STUDY

Vaccinating during pregnancy is safe for both of you. In fact, vaccination is one of the most important things that you can do to protect your health and your baby's health. Keep in mind that vaccines have been safely given to millions of pregnant women for more than 50 years.

Specifically, both flu and Tdap vaccination in pregnancy have been rigorously studied and both have been found to be safe for both mom and baby. Further, no increased risk for complications like miscarriage, preterm delivery, or stillbirth have been found for either vaccine.

What stands out to you about what I shared?

It is a relief to hear that this has been looked at and you are confident about their safety. But how does this benefit my baby?

Great question.

CASE STUDY

The flu can pose significant risks for pregnant women, and getting vaccinated is a safe and effective way to protect you both from this disease. Getting vaccinated can greatly reduce the chances of flu-related complications. In fact, by you getting vaccinated, you reduce your baby's risk of being hospitalized for flu by 70% in the first six months of life. Additionally, getting a Tdap vaccine during pregnancy provides protection to baby against whooping cough, also known as pertussis. This disease can be particularly dangerous in infants. So, the protection you can pass on to baby now by getting vaccinated, is especially important and could be life-saving to baby in the first few months of life.

CASE STUDY

I see getting vaccinated against flu and whooping cough during pregnancy as a crucial aspect of your prenatal care. I recommend vaccination as standard practice to all my patients. But ultimately it is your decision whether or not to get vaccinated. What would you like to do today?

Your recommendations are important to us. But, I think I need to take some time to think about it.

Absolutely. Can I send some resources home with you that I think may be useful as you make your decision? I would like to keep the conversation going on this important decision, can we discuss this at your next appointment?

Absolutely. Thank you for taking the time to discuss my concerns today.

What else can I do to increase vaccine coverage in my clinic?

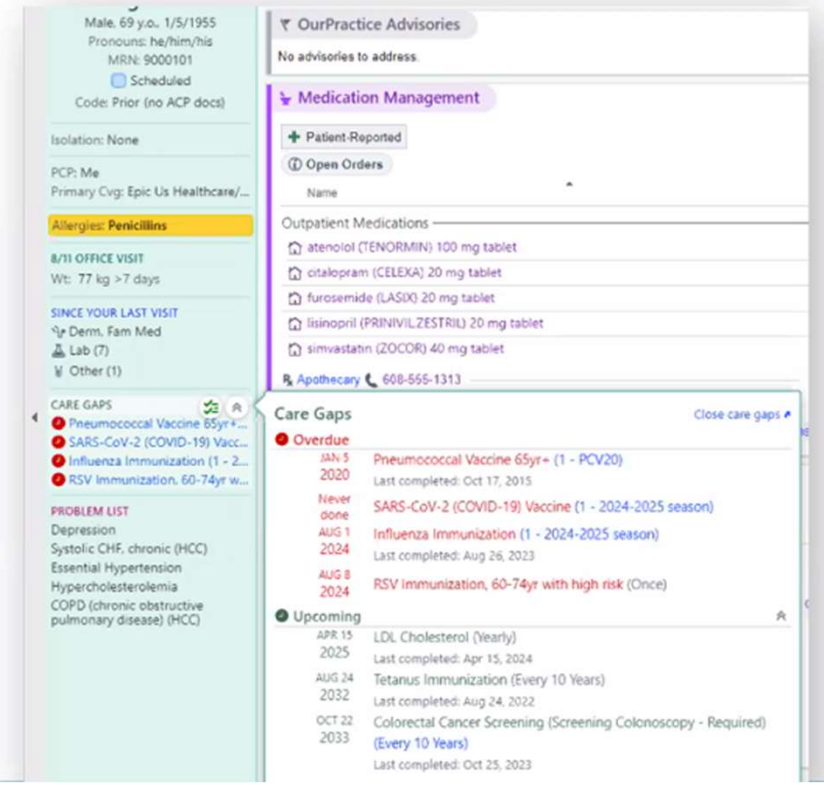
Use these tools and tips

- **Reminder/recalls:** Send when immunization are available
- **Clinical decision support tools:** Standing orders, Order Sets, "Care Gaps" to make administration easier
- **Continue to recommend immunizations to unvaccinated patients**, even if they decline the first time
- **Close the care loop with pharmacies:** Get to know your pharmacy-immunizing partners & how you can collaborate to protect more people in your community

Include on prescription or After-Visit-Summary if sending a patient to a pharmacy for RSV immunization:

- Risk factors
- Pregnancy status (including gestational age)
- "Pfizer Abrysvo" if pregnant

"Care Gaps" Feature on Electronic Health Records



Questions?

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