Preparing your pregnant patients for the 2024 – 2025 Respiratory Season

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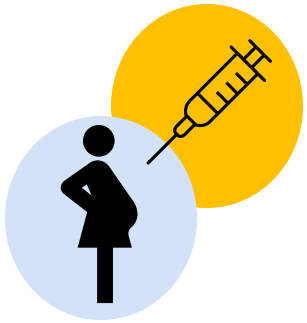
Disclosures

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

I have no relevant financial relationships to disclose.

Immunization Recommendations for Pregnant People: Overview



Vaccines recommended routinely during pregnancy

VACCINATION	1ST TRIMESTER	2ND TRIMESTER	3RD TRIMESTER
COVID-19	☑	☑	☑
FLU (Seasonal Inactivated Influenza)	☑	☑	☑
TDAP (Tetanus, diphtheria, and acellular pertussis)			☑
RSV (Respiratory Syncytial Virus)			☑

Immunization during pregnancy provides dual protection

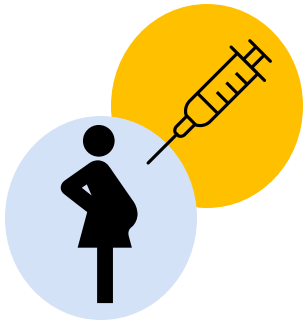
Enhanced risk of infectious morbidity during pregnancy

Gap immunity during early infancy

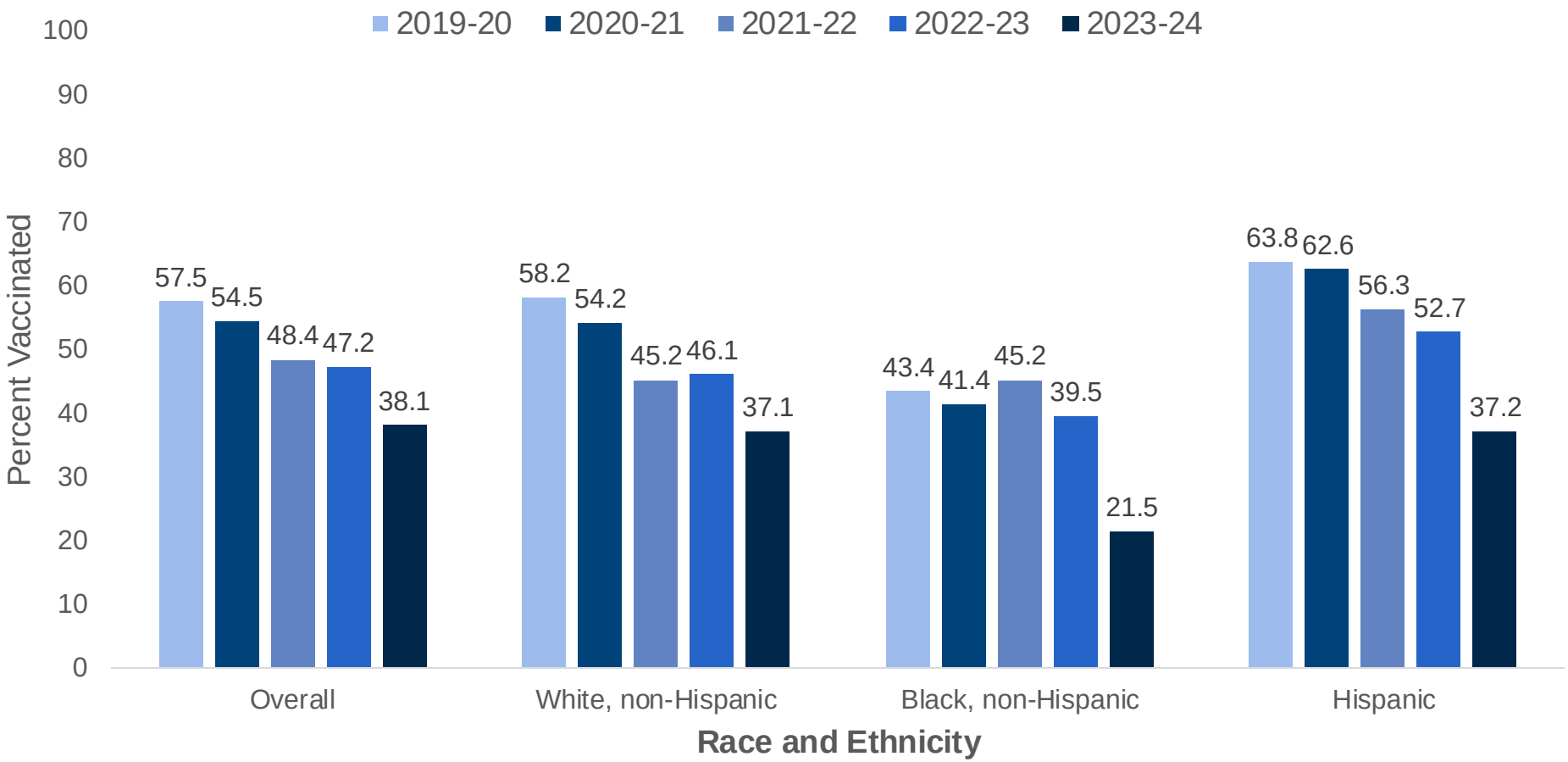
Dual protection through birthing person immunization

Promotion of life-long maternal and infant health and well-being

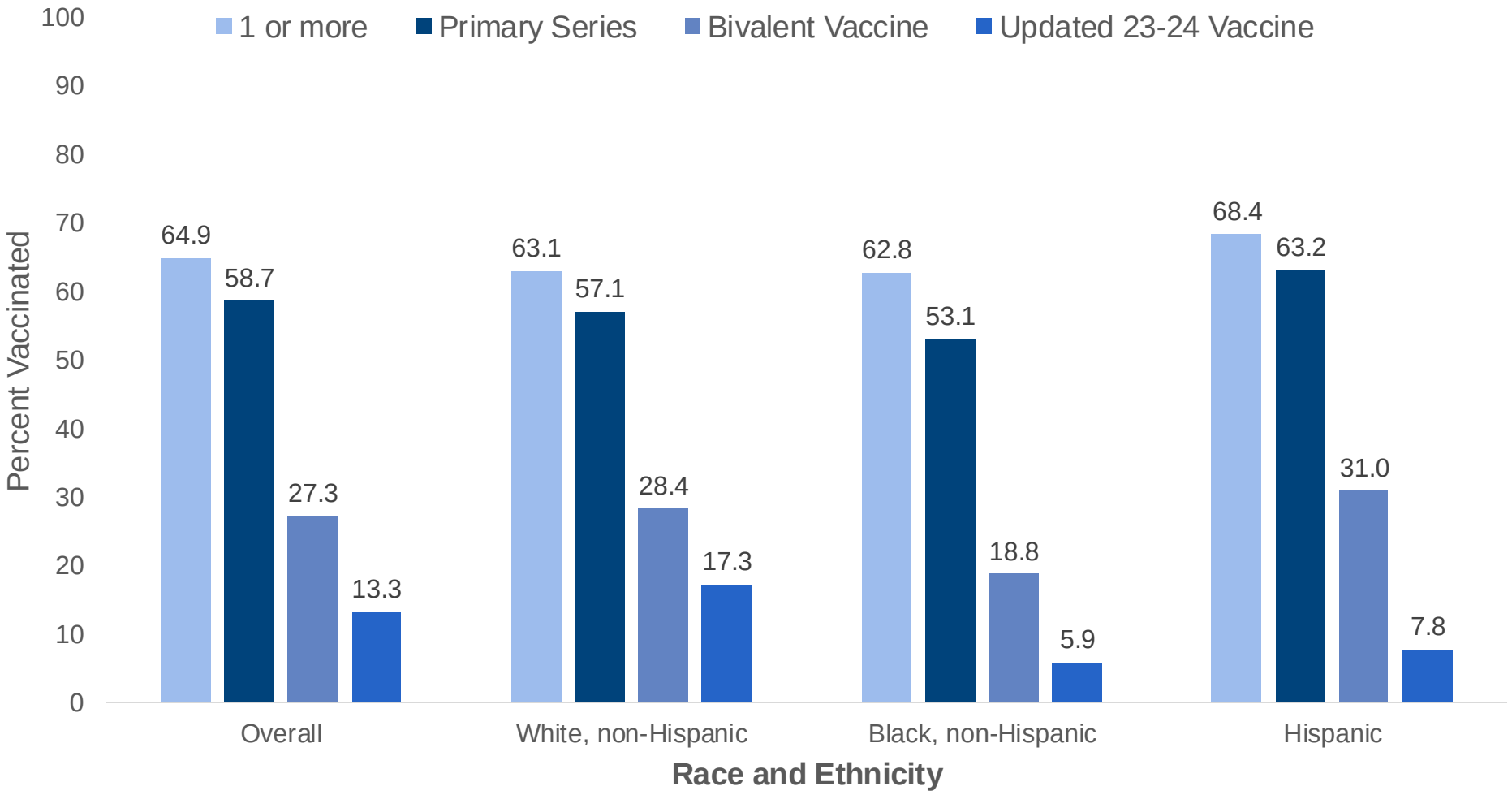
Pregnancy Vaccination Coverage: 2023 – 24 Respiratory Season



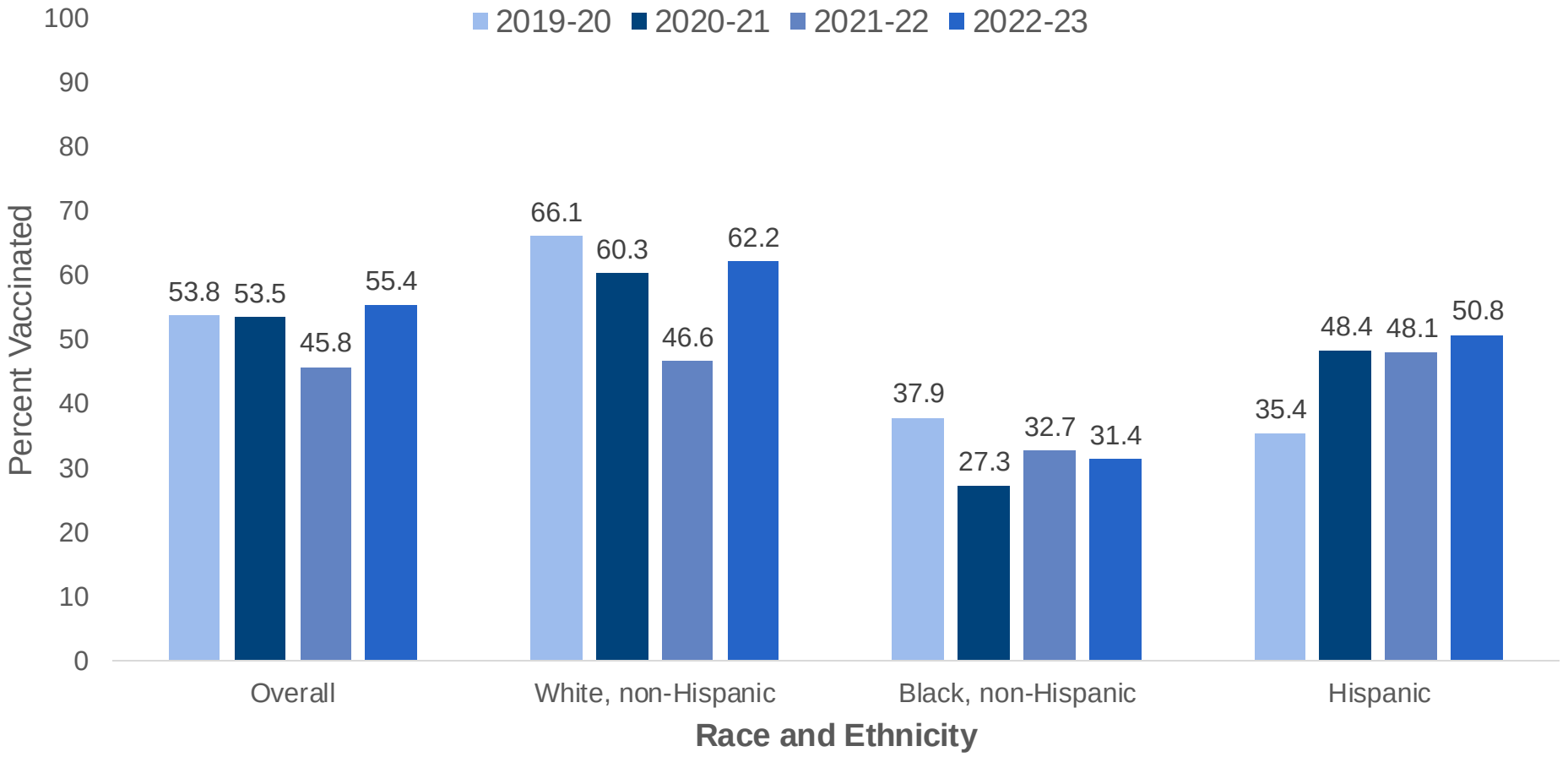
Influenza vaccine coverage among pregnant women by race/ethnicity, 2019 – 20 through 2023 – 24 influenza season



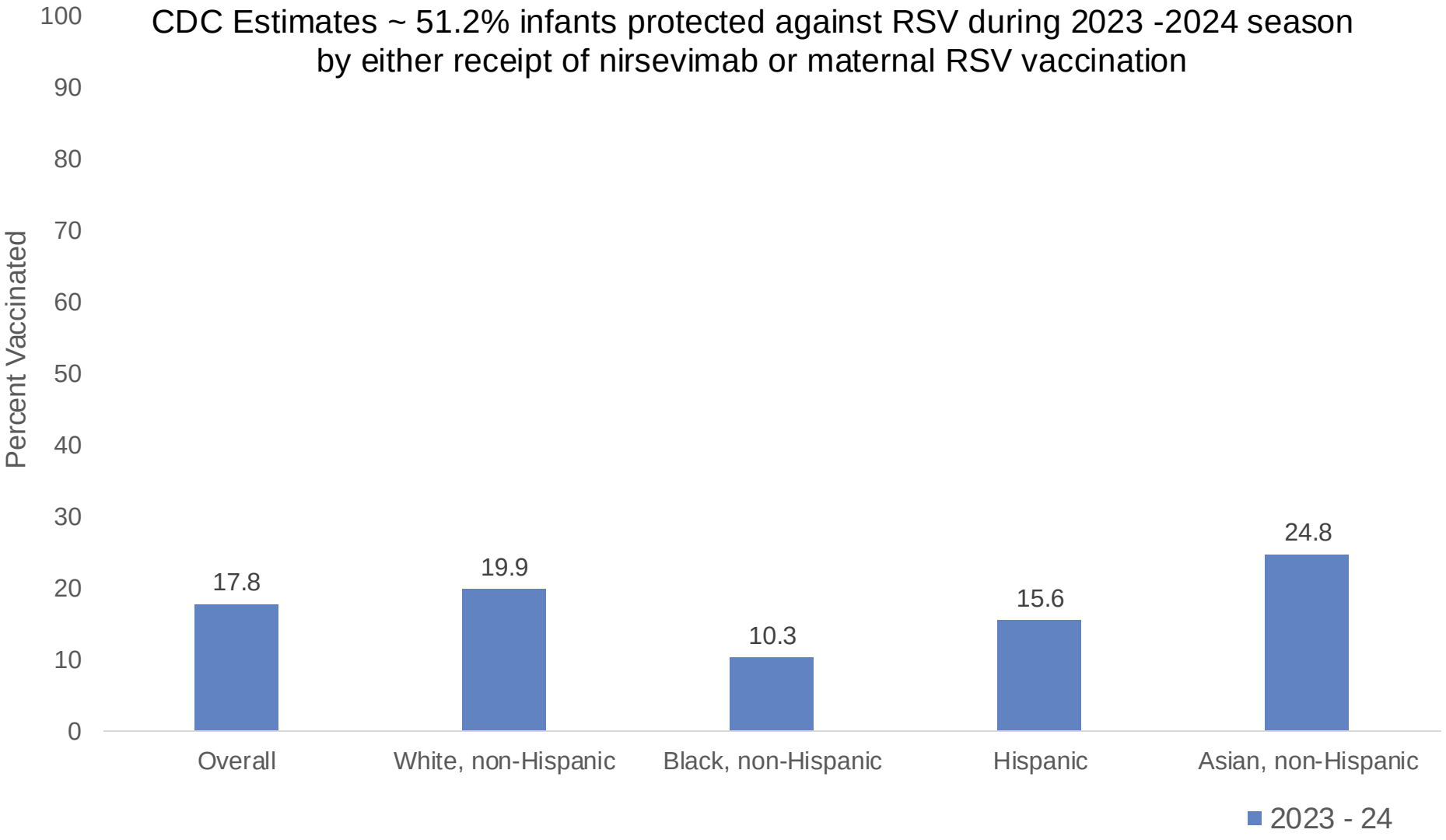
COVID-19 completed series vaccine coverage among pregnant women by race/ethnicity, 2023 – 24



Tdap vaccine coverage among pregnant women by race/ethnicity, 2019 – 20 through 2022 – 23 influenza season



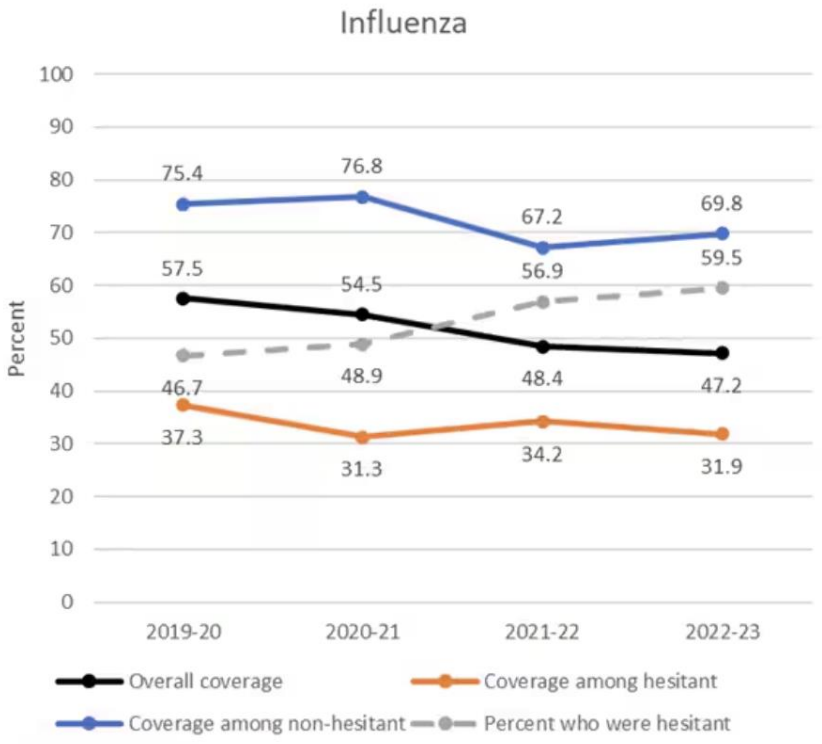
Respiratory Syncytial Virus vaccination coverage among pregnant women by race/ethnicity, 2023 – 24 RSV season

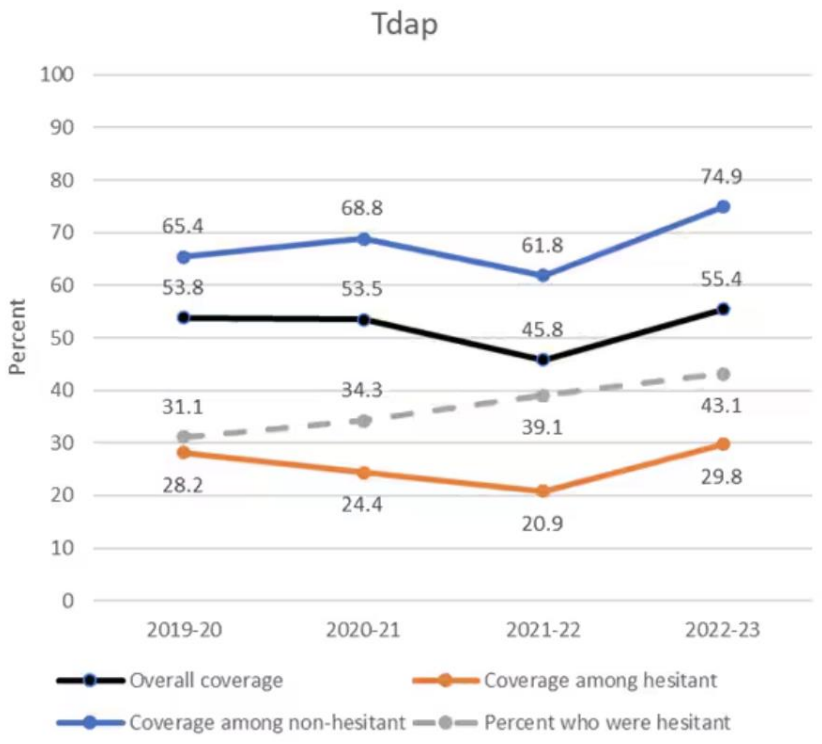


Immunization and the Implementation Dilemma

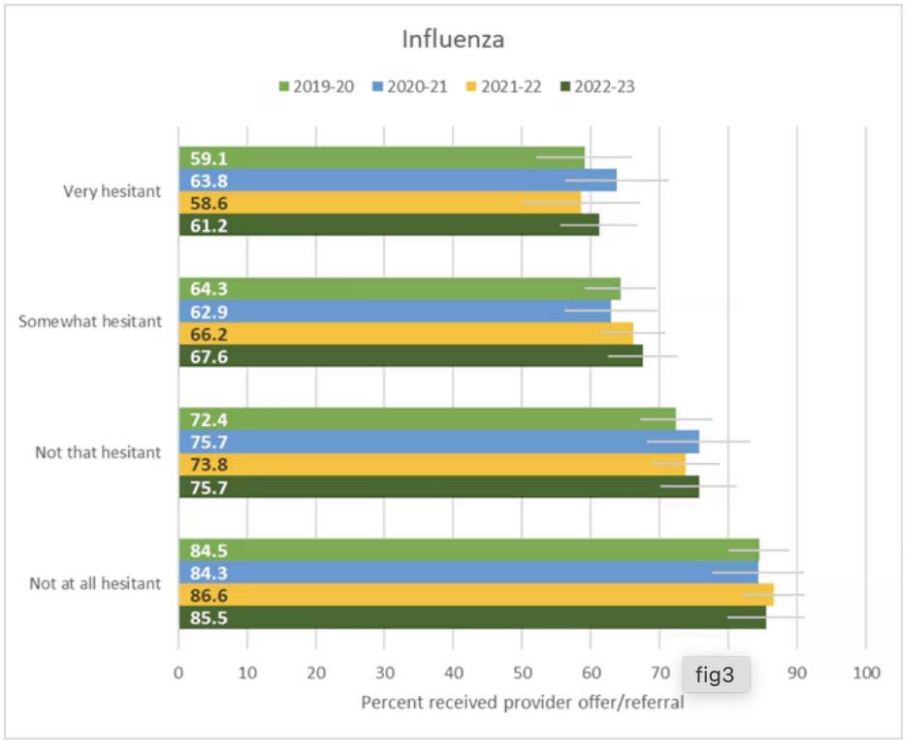
- Increasing number of immunization products during pregnancy
  - Lack of data on co-administration
- Lack of awareness among healthcare providers (including providers who do and do not routinely provide prenatal care)
- No universal financing mechanism for vaccination during pregnancy
  - No standardized pathway for distribution or access (vaccination through clinic or retail pharmacy)
  - Inequities in availability and allocation
- Lack of linked maternal-infant health records
- Patient and provider vaccine hesitancy

Trends in influenza and Tdap vaccine hesitancy and coverage among pregnant individuals, United States, 2019–20 through 2022–23 respiratory seasons





Provider referral increases vaccine uptake, even among vaccine hesitant



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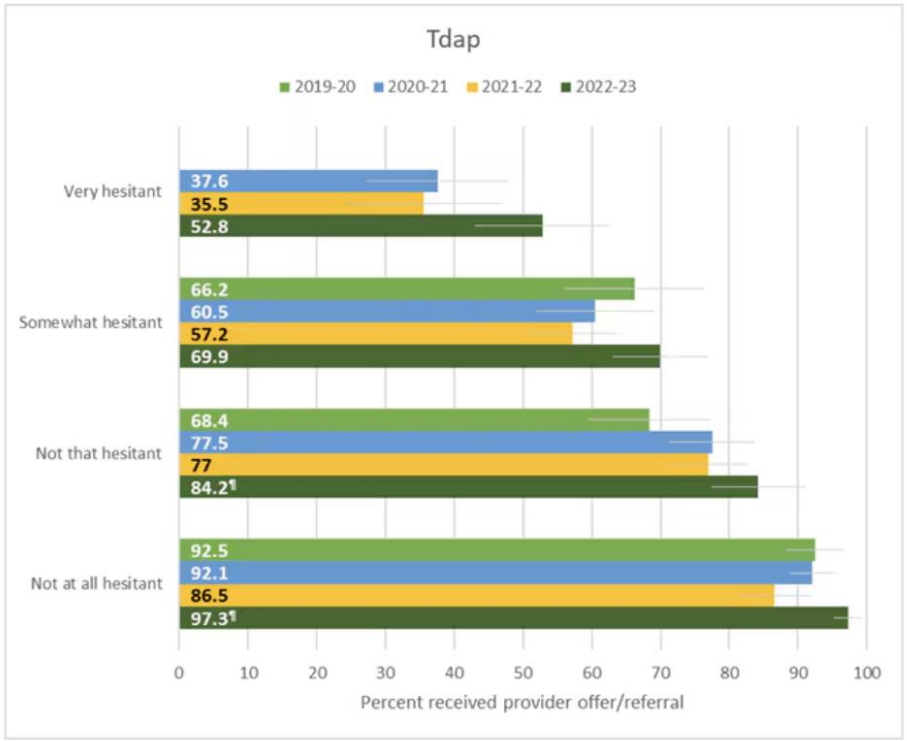
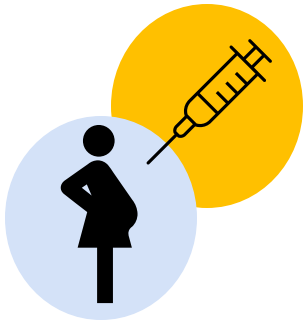


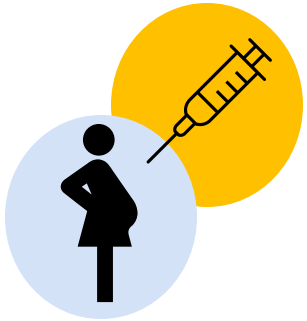
Prenatal care providers play a vital role in improving vaccine acceptance during pregnancy

- **Engage in vaccine counseling early and frequently**
  - Leverage frequency of prenatal care to elicit concerns and provide guidance
- **Provide strong recommendations for vaccines during pregnancy**
  - Patients who receive recommendations for vaccines from their obstetric provider are more likely to receive vaccines
  - Provide a strong recommendation to all pregnant patients
- **Affirm maternal and infant health benefits**
  - Protective messaging shown to be more effective in accepting vaccine
  - Affirming the role of all vaccines administered to pregnancy to protect both birthing person and infant
  - Emphasize the role of vaccines towards long term maternal and infant health outcomes (such as reducing the risk of chronic lung conditions)
- **Acknowledge the importance of vaccination towards reducing infectious-related health disparities**
  - Use as your own motivation to continuously engage over the spectrum of care

Pregnancy Vaccination Recommendations: 2024 – 25 Respiratory Season



Respiratory Syncytial Virus Immunization



Recommendations for Infant Protection Against RSV

- All infants should be protected against RSV using one of two products
- The bivalent RSVpreF vaccine (Abrysvo/Pfizer) is recommended to be administered as a one-time dose, using seasonal administration to pregnant persons between 32 0/7 and 36 6/7 weeks gestational age
  - Seasonal administration: September through end of January in most of the continental United States
- Nirsevimab is the monoclonal antibody directed against the RSV F protein, marketed as Beyfortus/ Sanofi-Pasteur
  - Administered from October through end of March in most of the continental United States
- Either maternal vaccination with Abrysvo or infant immunization with nirsevimab is recommended
  - With few exceptions, most infants will not need both

Maternal RSV Vaccine Safety: Risk of Preterm Birth

- In clinical trials more preterm births were noted among Pfizer RSV vaccine recipients compared to placebo (differences not statistically significant)
  - In the clinical trials participants were enrolled, and vaccines were administered from 24 through 36 weeks gestation
  - FDA approval window from 32 0/7 through 36 6/7 to mitigate the observed imbalance in preterm birth
- Preliminary findings in the Vaccine Safety Datalink (VSD) suggest that the incidence of preterm births is **4.1%** among pregnant persons who received Pfizer RSV vaccine during the 2023-2024 respiratory season
  - This is within the expected range of the incidence of preterm births at 32 0/7 – 36 6/7 weeks' gestation (3.1 - 6.1%) before introduction of this vaccine

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

Maternal RSV Vaccine Safety: Revaccination in subsequent pregnancies

- Additional data are needed prior to recommending RSV vaccine in subsequent pregnancies
  - Antibody data in pregnant people and infants with vaccination during subsequent pregnancies
  - Safety data (e.g. reactogenicity) with vaccination during subsequent pregnancies
  - Continuing surveillance regarding preterm birth

Maternal RSV Vaccine Safety: Reactogenicity Events

- Among reports received in VAERS after maternal Pfizer RSV vaccine, the most frequent adverse events reported were local and systemic symptoms (e.g., headache) and pregnancy specific conditions (e.g., preterm delivery)
  - Expected for a vaccine recommended for pregnant persons at 32-36 weeks' gestation
  - No verified reports of Guillain Barré syndrome

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

Recommendations for RSV Vaccination During Pregnancy

- Can be administered to any birthing persons **who has not previously received Abrysvo** between 32 0/7 – 36 6/7 weeks
- **Pregnant patients who received an RSV vaccine during a previous pregnancy are not recommended to receive additional doses during future pregnancies**
- Approved for seasonal administration (September – January)
- Can be co-administered with other routine immunization products in pregnancy (Tdap, COVID-19, influenza, RhoGAM)
- Patients should be counseled regarding safety and efficacy
- Patients should be counseled regarding the option for nirsevimab
- Providers should ensure that birthing patients are receiving the RSV vaccine made by **PFIZER (RSVPreF, Abrysvo)** and not GSK or Moderna

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

What is Nirsevimab?

- Monoclonal antibody directed against the RSV F protein, marketed as Beyfortus
  - Given to infants up to 8 months born during or entering their first RSV season whose birthing parent did not receive RSVPreF Vaccine or was vaccinated within 14 days of delivery
  - Given to infants with high-risk conditions up to 19 months entering their second RSV season
  - RSV season for administration is October – March in most of the continental United States
  - Single IM injection of 50mg (infants who weight < 5kg) or 100mg (infants who weight ≥ 5kg)
  - Two separate 100mg IM injections for infants entering their second season (200mg)
- Reduces the risk of medically-attended respiratory infections from RSV by 79% in recipients[1]

Real World Effectiveness of Nirsevimab

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)

Infant RSV Protection Challenges

CDC Alert regarding nirsevimab shortage

Distributed via the CDC Health Alert Network
October 23, 2023, 3:30 PM ET
CDCHAN-00499

Summary

The Centers for Disease Control and Prevention (CDC) is issuing this Health Alert Network (HAN) Health Advisory to provide options for clinicians to protect infants from respiratory syncytial virus (RSV) in the context of a limited supply of nirsevimab, a long-acting monoclonal antibody immunization product recommended for preventing RSV-associated lower respiratory tract disease in infants.

In the context of limited supply during the 2023–2024 RSV season, CDC recommends prioritizing available nirsevimab 100mg doses for infants at the highest risk for severe RSV disease: young infants (age <6 months) and infants with underlying conditions that place them at highest risk for severe RSV disease. Recommendations for using 50mg doses remain unchanged at this time. Avoid using two 50mg doses for infants weighing ≥5 kilograms (≥11 pounds) to preserve supply of 50mg doses for infants weighing <5 kilograms (<11 pounds). Providers should be aware that some insurers may not cover the cost of two 50mg doses for an individual infant.

State-supplied doses of nirsevimab will be available to order in the MIIS starting on September 3rd.

Update on Nirsevimab for the 2024-2025 Respiratory Season

Dear Provider,

Respiratory syncytial virus (RSV) is a major cause of childhood illness and the leading cause of bronchiolitis and pneumonia in children under one year of age. RSV infection can cause life-threatening respiratory problems in infants, which frequently require hospitalization, mechanical ventilation, or admission to an ICU. In the United States, RSV is the most frequent reason for hospitalization in a child's first year of life. In some cases, RSV infection in infants is fatal.

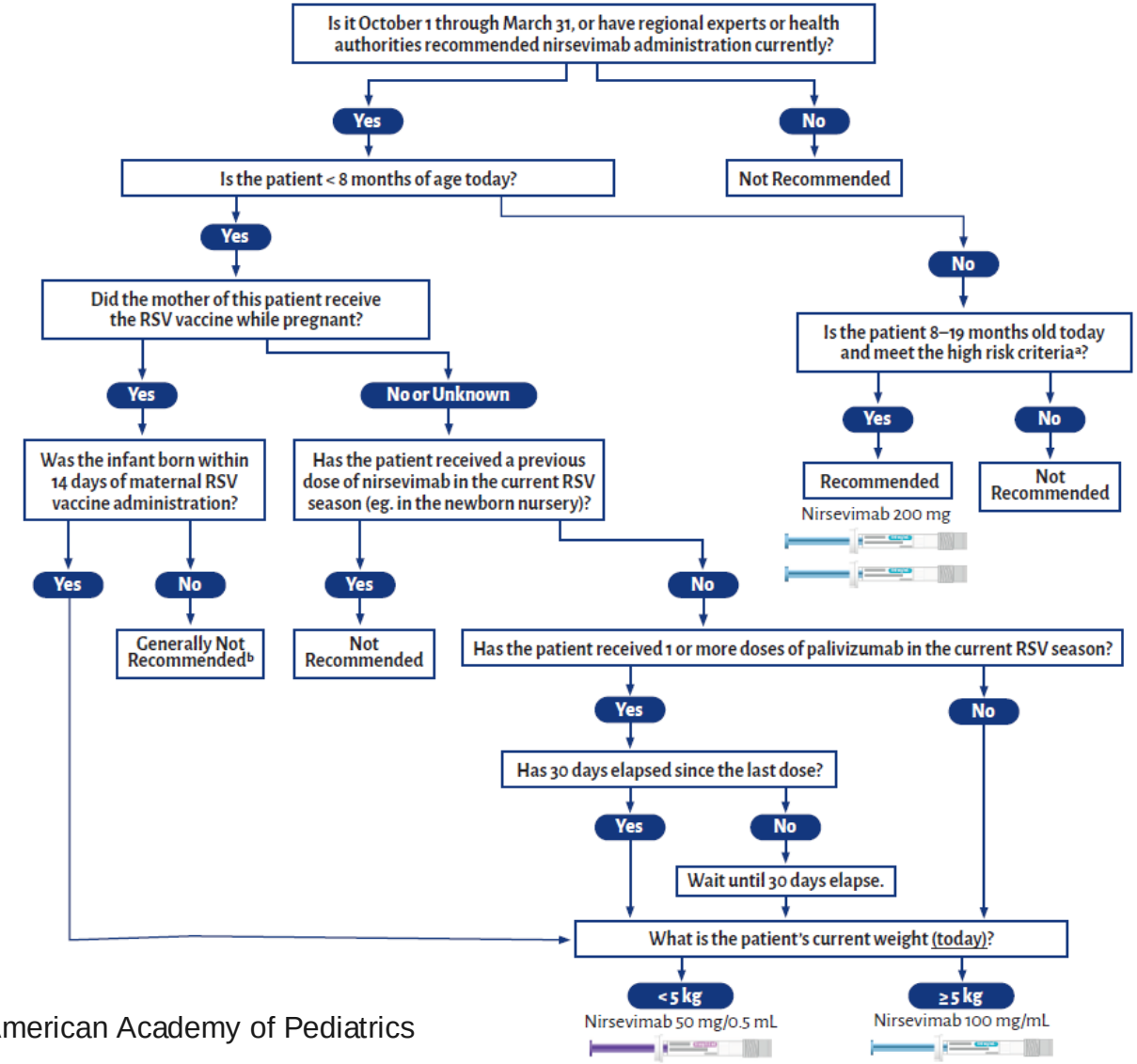
Nirsevimab (Beyfortus, Sanofi/AstraZeneca) is a long-acting monoclonal antibody against RSV given to infants to prevent severe disease. Successful implementation of newborn nirsevimab immunization is recommended and has the potential to have a major positive impact on the health of children.

State-supplied doses of nirsevimab will be available to order in the MIIS starting on September 3rd. State-supplied nirsevimab doses must be administered in accordance with the updated Childhood and Adult Availability Tables. Sites with nirsevimab products (Beyfortus 50mg or Beyfortus 100mg) still in inventory from the 2023-2024 Respiratory Season should administer those doses first, before replenishing their stock with additional doses ordered during the 2024-2025 Respiratory Season.

Comparing *Benefits and Concerns* for each product

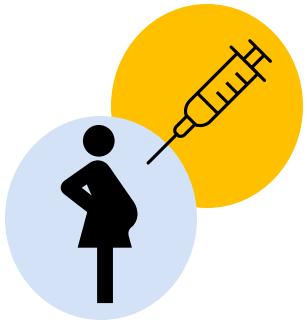
	Maternal Vaccine (RSVPreF, Abrysvo)	Infant Monoclonal Antibody (Nirsevimab, Beyfortus)
Benefits	• Provides immediate protection for infant at birth (if maternal vaccination occurred ≥14 days before birth) • High efficacy	• Protection may last longer than maternal vaccination • Direct antibody transfer to infant rather than passive transfer of maternal antibodies • Highly effective
Concerns	• Reduced antibody transfer if delivery of infant is <14 days after maternal immunization or maternal immunocompromised state • Need for surveillance of birth outcomes	• Requires infant injection • Serious hypersensitivity reactions – urticaria, dyspnea, cyanosis, hypotonia (product labeling updated)

Infant RSV Immunization Guidance



Adapted from the American Academy of Pediatrics

COVID-19



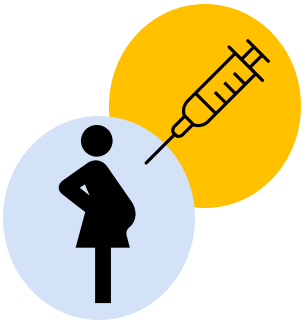
Recommendations for COVID-19 Vaccination

- The FDA has approved and authorized 2024–2025 Moderna and Pfizer-BioNTech COVID-19 vaccines.
- Targeted against KP.2 Variant (+KP.3.1.1, account for 14-48% of COVID-19 infections as of August 20)[1]
- The CDC recommends[2] that all people 6 months and older receive any of the authorized 2024 – 2025 updated COVID-19 vaccines made by Pfizer-BioNTech or Moderna
- All pregnant persons are included in this recommendations
  - The vaccine can be administered in any pregnancy trimester
- People 12 years and older are “up to date” when they have received 1 dose of either vaccine
- CDC recommendation for Novavax vaccine pending FDA approval

COVID-19 vaccination is effective at preventing severe illness and complications during pregnancy

- No difference in safety or immunogenicity compared to nonpregnant adults[1]
  - No difference in rates of injection site pain, headache, fatigue, fever in pregnant compared to nonpregnant adults
- No increased risks of miscarriage or pregnancy loss[2]
  - National surveillance data demonstrate risk of miscarriage by 20 weeks 50% lower in vaccinated pregnant individuals compared to nonpregnant adults
- Increased protection against infection and severe disease[3]
  - 2-3-fold reduced risk of infection and hospitalization
- Effectiveness of vaccination against *infant* hospitalization[4]
  - 50-80% reduced risk against infant hospitalization, ICU admission, mechanical ventilation

Flu



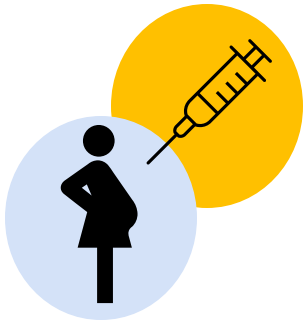
Recommendations for Seasonal Inactivated Influenza Vaccination

- All influenza vaccines marketed in the United States for the 2024 – 25 season will be trivalent
- Routine annual influenza vaccination is recommended for all persons aged ≥6 months without contraindications.
  - Ideally, vaccine is administered from September to October, based on local transmission, and ongoing throughout influenza season
  - The vaccine can be administered in any pregnancy trimester
  - If a pregnant person is in their third trimester in August and unvaccinated, SIIV can be offered to enhance passive immunity for their infant
  - The only contraindications to receiving SIIV is prior anaphylaxis
    - Precaution can be used for persons with history of Guillain-Barre Syndrome within 6 weeks of a previous SIIV
    - Persons with an egg allergy should receive SIIV in a monitored, health care setting
  - No adverse pregnancy outcomes have ever been attributed to SIIV

2009 Pandemic H1N1 and unique threats to pregnancy

- **Emerging understanding of pregnancy specific threats**
  - 5% of all H1N1 influenza deaths were among pregnant persons who only comprised 1% of the entire population
  - 22.6% of all H1N1 ICU admissions among pregnant persons
  - Increased rates of spontaneous abortion, preterm birth, low birth weight, stillbirth, neonatal death
- **Vaccination associated with**
  - Reduced influenza hospitalization by 39 – 47%
  - Increased infant birth weight, reduced preterm birth and fetal death
  - Reduced hospitalization by 90% in infants up to 6 months of age, highest when vaccinated in the third trimester
- **Two for the price of one benefit for vaccination during pregnancy**

Tdap

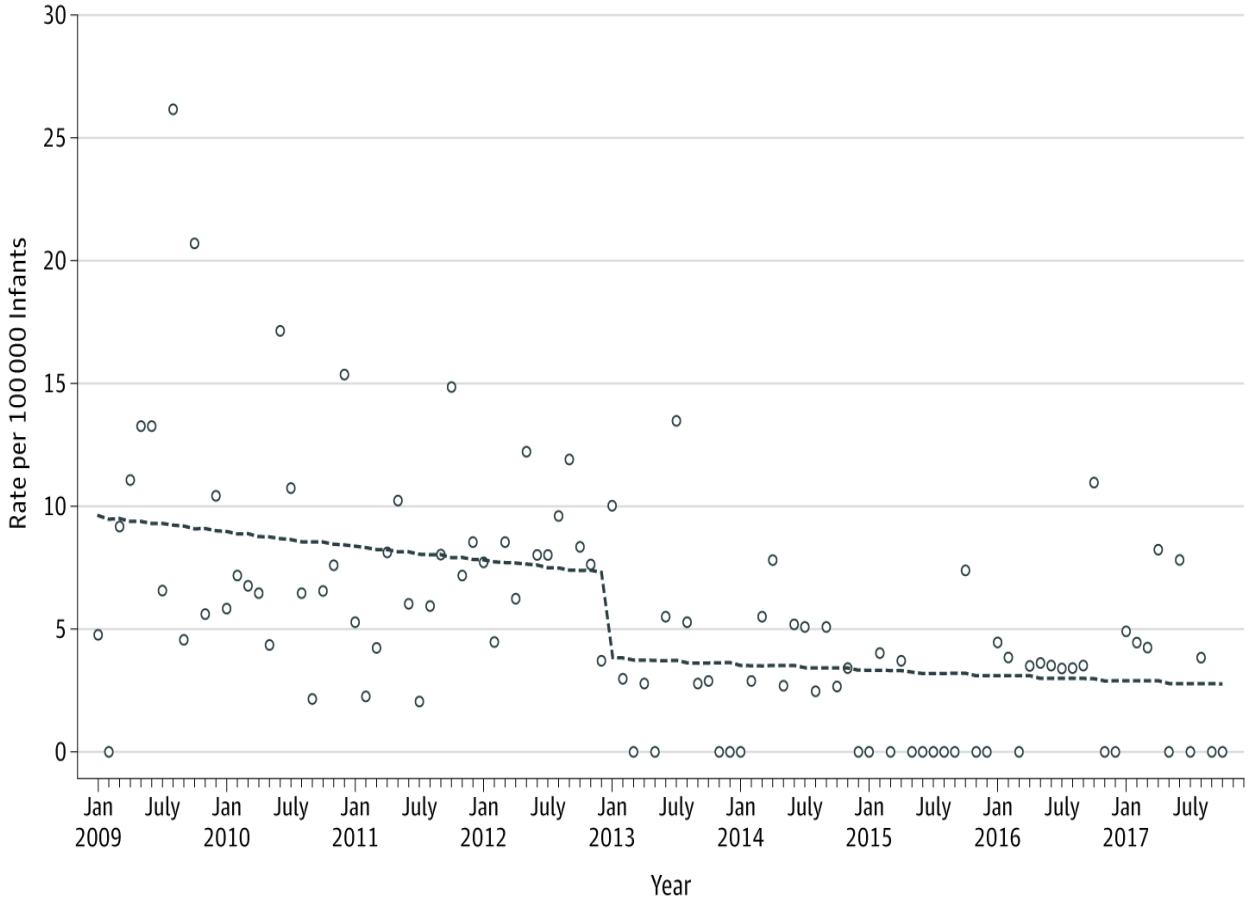


Recommendations for Tdap vaccination

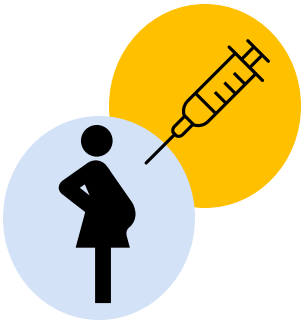
- Tetanus, diphtheria, and acellular pertussis vaccination is recommended in every pregnancy between 27 0/7 to 36 6/7 weeks gestation
  - Ideally Tdap is administered in the early part (e.g. 27 0/7 to 30 0/7 weeks)
  - Can be offered prior to 27 weeks if unvaccinated and concern for local outbreak or for pre-exposure prophylaxis
- Tdap can also be offered during delivery hospitalization for birthing persons who plan to parent and have never received prior Tdap vaccine
- For persons with unknown or incomplete Tetanus vaccination
  - Administer three vaccines containing tetanus and reduced diphtheria toxoid (0 weeks, 4 weeks, 6 months)
  - Tdap should replace the dose given between 27 – 36 weeks

Pregnancy dose Tdap most effective in reducing infant hospitalization in first 2 month of life

- Vaccination during pregnancy confers protection against infant pertussis-related hospitalization
  - 8.4 per 100,000 to 3.3 per 100,000
  - 48% reduction in infant pertussis hospitalization



Provider Counseling Points for Maternal and Infant Protection this Respiratory Season

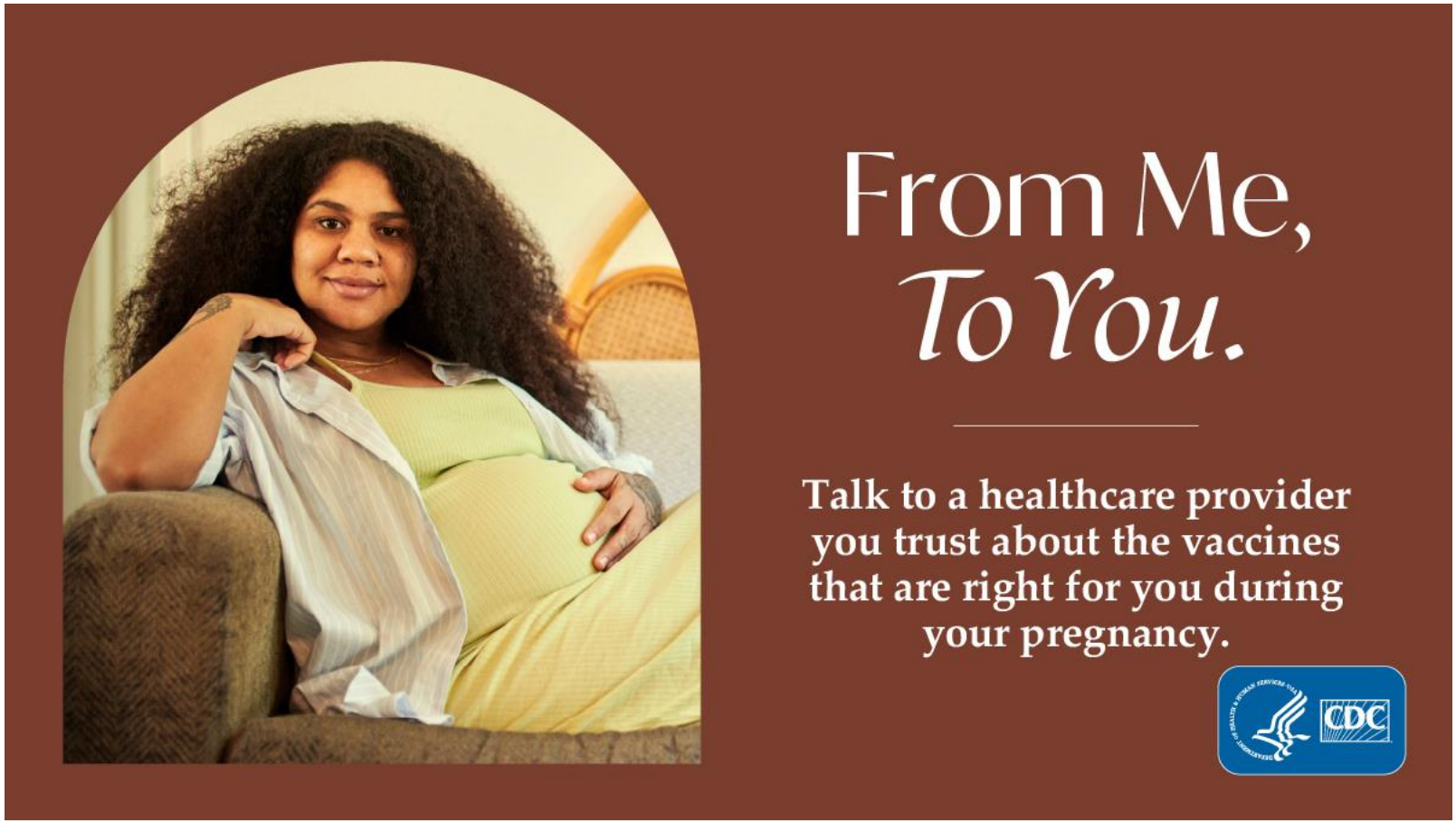


Provider Counseling Points for Maternal Immunization

- ✓ Providers should counsel pregnant persons and strongly recommend that pregnant persons follow CDC recommendations for vaccination in pregnancy including vaccines against RSV*, seasonal influenza, COVID-19, and pertussis
- ✓ All vaccines have been shown to be safe and effective
- ✓ COVID-19 and Flu vaccines provide maternal protection against severe respiratory disease and are associated with improved birth outcomes (e.g. reduced risk of preterm birth, low birthweight, stillbirth)
- ✓ All vaccines provide protection to infants up to 6 months of age against severe respiratory disease

*Not recommended if received Abrysvo in a previous pregnancy

“From Me, *To You*”



Additional Resources

Centers for Disease Control and Prevention:
https://www.cdc.gov/rsv/index.html

ACOG, AAFP, ACNM, SMFM, AWOHN Statement:
https://www.acog.org/-/media/project/acog/acogorg/files/pdfs/news/rsv-joint-statement-2023.pdf

ACOG Practice Advisory on RSV Vaccine:
https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2023/09/maternal-respiratory-syncytial-virus-vaccination

SMFM Statement on RSV Vaccine:
https://www.sciencedirect.com/science/article/pii/S0002937823008013?ref=pdf_download&fr=RR-2&rr=836b57da6d973b8e#bib21