SMFM Statement: Respiratory Syncytial Virus Vaccination in Pregnancy

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This guidance was developed by the Society for Maternal-Fetal Medicine (SMFM) Committee on Infectious Diseases and Emerging Threats with the assistance of Naima T. Joseph, MD, MPH and Brenna L. Hughes, MD, MSc.

Background

Respiratory syncytial virus (RSV) is a leading cause of lower respiratory tract illness in children under 5 years. Before RSV immunization products were widely available in the US, RSV contributed to approximately 58,000 – 80,000 hospitalizations in children under 5 years, with infants aged 6 months and younger experiencing the most severe morbidity and mortality. Until recently, prevention was limited to infants with high-risk conditions.[1]

On September 22, 2023, the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) recommended the bivalent recombinant respiratory syncytial virus prefusion F protein subunit (RSVpreF) vaccine (Abrysvo® by Pfizer) for pregnant patients from 32 0/7 weeks through 36 6/7 weeks of gestation, using seasonal administration, to prevent RSV lower respiratory tract infection in infants.[1] Administration of a monoclonal antibody in infants, either nirsevimab (Beyfortus® by Sanofi) or clesrovimab (Enflosia by Merck), is an alternative passive immunization strategy for infants whose birthing parent was either not vaccinated this pregnancy, or was vaccinated within two weeks of delivery, a timeframe too short for effective transplacental transfer of protective antibodies.[2,3,4]

Vaccine Safety and Efficacy

Maternal Immunization with the RSVpreF Vaccine
In the final analysis of the MATISSE study, the efficacy of RSVpreF vaccine against medically attended severe RSV-related illness in infants was 82.4% (95% Confidence Interval (CI), 57.5–93.9) within 90 days of birth, and 70.0% (95% CI, 50.6–82.5) within 180 days of birth.[5] Side effects from maternal vaccination were low; however, there was a signal regarding the risk of preterm birth that did not reach statistical significance.[1]

In the preterm birth analysis from the MATISSE study, a nonsignificant difference in preterm birth was observed in the vaccine group (5.7%) versus the control group (4.7%) (relative risk 1.20, 95% CI, 0.98–1.46).[5,6] The data on spontaneous versus indicated preterm birth were not included, and this difference was only observed in low- and middle-income

countries participating in the MATISSE trial.[5,6] Of these, 60% of preterm births occurred more than 30 days following vaccination, and 90% occurred between 34 to 37 weeks of gestation. There was no difference in neonatal deaths (<0.3%).[6] Furthermore, post-marketing observational studies found that there was no significant association between administration of the RSVpreF vaccine and preterm birth.[7,8]One retrospective cohort study among 647 pregnant patients eligible for the RSVpreF vaccine found that preterm delivery occurred in 35 out of 414 patients who received the RSVpreF vaccine (8.5%) and 43 out of 233 patients who did not receive the vaccine (18.5%).[7] Investigators conducted a nested case-control analysis with the outcome of preterm birth, and found there was no significant association between maternal immunization and preterm birth (adjusted odds ratio 1.03, 95% CI, 0.55–1.93).[7] In another retrospective observational cohort study among 2973 pregnant patients eligible for the RSVpreF vaccine, 60 out of 1026 patients (5.9%) who received the vaccine experienced preterm birth, and 131 out of 1947 patients (6.7%) who did not receive the vaccine experienced preterm birth.[8] After adjusting for confounders (adjusted odds ratio 0.87, 95% CI, 0.62–1.20) and addressing immortal time bias, investigators found no association between RSVpreF vaccination and preterm birth.[8]

Limited data available suggest improved transplacental transfer efficiency when vaccination occurs at a longer interval from delivery.[5,9] An observational study of real-world RSVpreF vaccine use in 124 pregnant patients during the first season of RSV vaccine availability in pregnancy suggested vaccination at least 5 weeks prior to delivery resulted in most efficient placental transfer of maternal antibody.[9] A secondary analysis of the MATISSE trial data had similar findings, reporting umbilical cord to maternal serum ratios of 1 only if vaccination occurred 30 days prior to delivery.[5] Thus, the limited available data regarding timing within the approved 32 0/7 through 36 6/7 week window may favor vaccination earlier within this window to achieve the most efficient transfer of maternal antibody to the neonate. Whether such efficient transfer is needed for neonatal and infant protection against moderate to severe RSV-related illness is currently not known, however.

Data regarding lactation and infant protection through breastmilk were not evaluated.[1] In addition, there are no efficacy data to date on the use of repeated administration of the RSVpreF vaccine.

Administration of Monoclonal Antibodies in Infants

Clinical trials for the two monoclonal antibody products for administration in infants also demonstrate efficacy against RSV-related medically attended lower respiratory tract infection (MALRI) in infants, infant hospitalization, and infant intensive care unit (ICU) admission, evaluated through 150 days of injection.

The efficacy of nirsevimab in preventing RSV-related MALRI in infants, where MALRI was defined as ≥1 indicators of lower respiratory tract infection (LRI) or severity, was 79.0% (95% CI, 68.5–86.1); efficacy in preventing infant hospitalization due to RSV was 80.6% (95% CI, 62.3–90.1); and efficacy in preventing infant ICU admission for RSV was 90.0% (95% CI, 16.4–98.8).[2]

The efficacy of clesrovimab in preventing RSV-related MALRI in infants, where MALRI was defined as ≥1 indicators of LRI or severity, was 60.4% (95% CI, 44.1–71.9); efficacy in preventing RSV-related MALRI in infants, where MALRI was defined as ≥2 indicators of LRI or severity, was 88% (95% CI, 76.1–94.0); efficacy in preventing infant hospitalization due to RSV-related LRI was 90.9% (95% CI, 6.2–96.5); and efficacy in

preventing infant ICU admission for RSV-related LRI was 91.7% (95% CI, 62.9–98.1).[10,11]

Impact of RSV Prevention Products on Infant Health
During the 2023–2024 and 2024–2025 respiratory disease seasons, an estimated 57% of infants were either born to a vaccinated pregnant patient or received nirsevimab, as reported during the June 2025 ACIP meeting.[12] Following introduction of the RSVpreF vaccine and nirsevimab for infants, rates of RSV-associated infant hospitalization decreased by approximately 30% to 40% among eligible infants and by 50% among infants 0-2 months of age, compared to rates prior to the availability of these immunization products.[12]

SMFM Recommendations

The Society for Maternal-Fetal Medicine (SMFM) recommends the RSVpreF vaccine (Abrysvo® by Pfizer) for pregnant patients from 32 0/7 weeks through 36 6/7 weeks of pregnancy, using seasonal administration, as a strategy to protect their infants from severe RSV disease.

- The RSVpreF vaccine (Abrysvo® by Pfizer) is the only approved vaccine for use in pregnancy. It is recommended for pregnant patients during RSV season (typically September 1st to January 31st in most parts of the United States) who do not have a plan for delivery in the next two weeks.
- Patients who have received the RSVpreF vaccine during a previous pregnancy are not recommended to receive additional doses during future pregnancies because there are no efficacy data on the use of repeated administration of the RSVpreF vaccine. Infants born to patients that were vaccinated during a previous pregnancy should receive nirsevimab or clesrovimab.
- Patients should be counseled regarding the benefits of maternal vaccination as a safe and effective way to prevent RSV-related lower respiratory tract disease in infants from birth through 6 months of age. Patients should be counseled that available studies have not demonstrated a definitive link between RSV vaccination in pregnancy and preterm birth.
- Patients should be counseled that although data on whether breastfeeding confers additional protection following maternal vaccination is lacking, additional protection against severe RSV disease for the infant is expected.
- Patients should also be aware of the option for two monoclonal antibodies, nirsevimab and clesrovimab, for infant protection against RSV-related illness. With few exceptions, infants of pregnant patients who received the RSVpreF vaccine should not receive nirsevimab or clesrovimab. Some implementation barriers, including cost or product availability, may preclude infant access to the monoclonal antibodies. Patients who have either already received the RSVpreF vaccine in a prior pregnancy or who opt for nirsevimab or clesrovimab should be advised to confirm availability through their birthing hospital or pediatrician.

These recommendations may be updated in the future as additional data become available. Please visit the American Academy of Pediatrics and the CDC for further information regarding the administration of nirsevimab and clesrovimab in infants.

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Suggested Citation

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