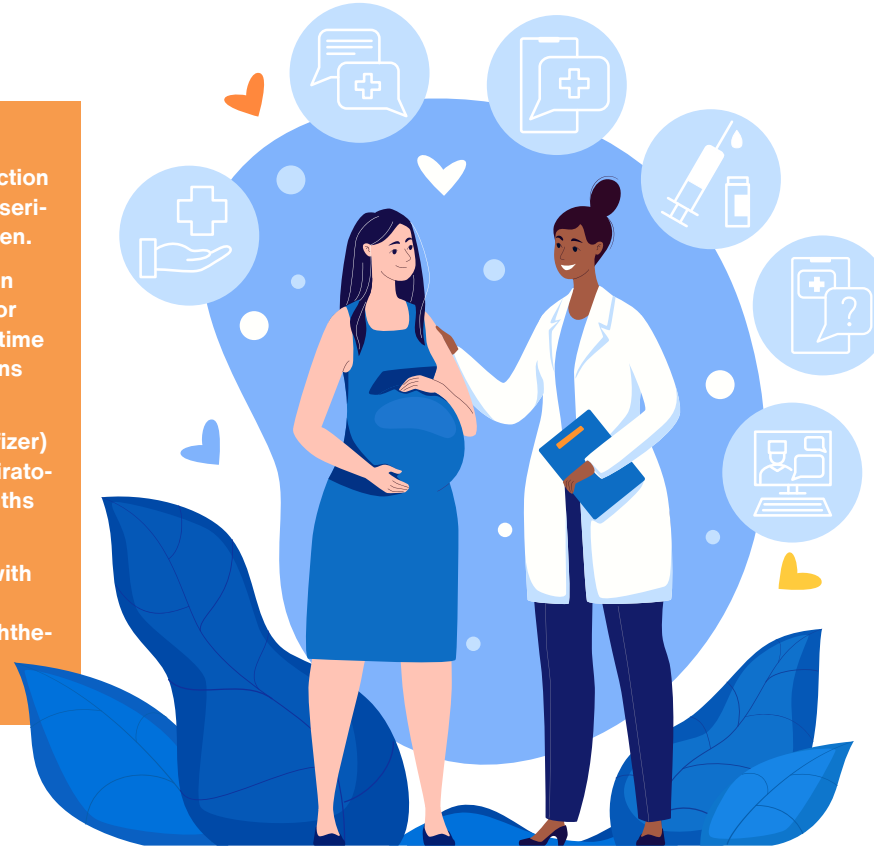
Vaccinating Pregnant Patients to Protect Their Newborns From RSV: A Conversation Guide for Pharmacists

Overview

- Respiratory syncytial virus (RSV) infection is common and can cause potentially serious illness in infants and young children.
- The U.S. Food and Drug Administration (FDA) has approved an RSV vaccine for pregnant patients (during a specified time of pregnancy) to protect their newborns from RSV disease.
- Maternal vaccination with Abrysvo (Pfizer) reduced the risk of severe lower respiratory tract disease in infants up to 6 months after birth.
- RSV vaccine can be coadministered with other vaccines recommended during pregnancy such as Tdap (tetanus, diphtheria, and pertussis), influenza, and COVID-19 vaccines.



Burden of RSV

RSV is a common respiratory virus that causes mild symptoms in most people. However, the virus can cause serious illness in infants and young children. The Centers for Disease Control and Prevention (CDC) estimates that in the United States, for children younger than 5 years old, 58,000 to 80,000 are hospitalized and 100 to 300 children die each year due to an RSV infection.

All children are at risk for severe illness from RSV, but the greatest risk can occur in several groups:

- **Infants born prematurely.**
- **Infants (i.e., younger than 12 months old), especially those 6 months and younger.**
- **Children who are immunocompromised.**
- **Children younger than 2 years old with chronic lung disease or congenital heart disease.**
- **Children who have neuromuscular disorders.**

By getting vaccinated, pregnant patients can protect their newborn babies because vaccine-induced antibodies pass through the placenta. Therefore, educating pregnant patients on how they can protect their babies from severe RSV illness is paramount.

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Key Counseling Pearls

- **Inform patients** that RSV causes a common and potentially serious respiratory infection in young infants.
- **Educate patients** that all children are at risk of severe illness from RSV.

Recommended Options for Preventing RSV Infections in Young Infants

In August 2023, FDA licensed the first and only RSV vaccine for pregnant patients (i.e., Abrysvo—Pfizer) to protect newborns and infants against severe RSV disease during the first 6 months after birth. Later that year, CDC recommended the use of a single dose of maternal RSV vaccine given to patients who are at 32 through 36 weeks' gestation when this coincides with September through January. The interval from September to January applies to the 48 contiguous states in the United States. The state health department should be consulted for preferred timing in Alaska and jurisdictions with tropical climates (e.g., southern Florida, Puerto Rico, U.S. Virgin Islands, Hawaii, Pacific islands).

Three RSV vaccines are licensed in the United States: Arexvy (GSK), mRESVIA (Moderna), and Abrysvo (Pfizer). Clinicians should be mindful that only Abrysvo includes maternal vaccination in its FDA-licensed labeling. None of the three RSV vaccines is licensed for use in infants.

Vaccinating the mother at least 14 days before giving birth protects the baby immediately at birth and persists through the first 6 months of life. Protection is not optimal if the infant is born sooner than 14 days after vaccination or if the mother's immune system fails to respond fully to vaccination.

An alternative to RSV vaccination of the mother is to give the long-acting antibody product nirsevimab (Beyfortus—Sanofi and AstraZeneca) to the newborn. Protection of the baby may last longer than via maternal vaccination. Protection provided by nirsevimab is likely most effective the weeks after it is given and wanes over time. However, families could have difficulty accessing the product if their health care providers do not yet stock nirsevimab.

Nirsevimab should be given to all infants born before gestation week 34 because Abrysvo cannot be given earlier than gestation week 32. Nirsevimab should also be given to all infants born in April through September, whose mothers will not be eligible for RSV vaccine. Refer to other resources from CDC for additional information about nirsevimab.

For patients who received the Abrysvo RSV vaccine during a previous pregnancy, repeat vaccination with another dose during subsequent pregnancies is currently not recommended because of a lack of data. Offspring from these subsequent pregnancies should receive nirsevimab.

Key Counseling Pearls

- **Ask pregnant patients:** "When are you due? How many weeks along in gestation are you?" From this information, calculate when the week 32 through week 36 window will occur.
- **Ask pregnant patients:** "Where do you reside?" If the 32 through 36 week window will fall between September through January in the 48 contiguous states plus Washington, DC (or during the interval recommended by public health officials in other jurisdictions), then patient is a candidate for maternal RSV vaccination. Note: A Maternal RSV Vaccine Planner is available at: https://abrysvomaternal.pfizerpro.com/resources/maternal-rsv-vaccine-planner
- **Inform patients** there is only one RSV vaccine that is FDA licensed for pregnant patients (i.e., Abrysvo—Pfizer) to protect newborns and infants against severe RSV disease during the first 6 months after birth.
- **Tell patients** that nirsevimab is another option which provides protective antibodies to the newborn soon after birth.

Effectiveness of the Maternal RSV Vaccine

The vaccine efficacy of Abrysvo was evaluated in a phase 3 study in which approximately 3,500 pregnant patients were administered the RSV vaccine compared with approximately 3,500 who were given a placebo. The vaccine was administered to pregnant patients at 24 through 36 weeks' gestation in this trial, so data are available for the entire population and those who specifically received the vaccine during the recommended interval of 32 through 36 weeks.

Abrysvo reduced the risk of severe lower respiratory tract disease by 81.8% at 90 days after birth and by 69.4% after 180 days after birth compared with placebo. In a subgroup analysis of infants born to patients who received the RSV vaccine at 32 through 36 weeks' gestational age (approximately 1,500 patients in each group), the risk of severe lower respiratory tract disease was reduced by 91.1% at 90 days after birth and by 76.5% at 180 days after birth, respectively, compared with placebo.

Safety of the Maternal RSV Vaccine

The most common adverse events observed after use of the RSV vaccine in pregnant patients were injection-site reactions such as pain, swelling, and redness, and systemic reactions such as fever, fatigue, headache, muscle pain, nausea, joint pain, diarrhea, and vomiting.

The prescribing information for Abrysvo does include a warning and precaution that discusses the potential risk of preterm birth, as a numerical imbalance in preterm births was observed with Abrysvo compared with placebo in clinical studies. Among pregnant patients in the clinical trial who received either the maternal RSV vaccine or a placebo during 32 through 36 weeks' gestation, preterm birth occurred in 4.2% of pregnant patients who received the RSV vaccine compared with 3.7% of pregnant patients who received the placebo. The labeling notes that available data are insufficient to establish or exclude a causal relationship between preterm birth and use of Abrysvo. Therefore, to avoid the potential risk of preterm birth with use of the vaccine before 32 weeks of gestation, the vaccine should be administered as indicated at 32 through 36 weeks' gestational age.

Key Counseling Pearl

- **Inform patients** that vaccination with Abrysvo (Pfizer) reduced the risk of severe lower respiratory tract disease in infants up to 6 months after birth.

CDC offers its V-safe smartphone-based safety monitoring system for RSV vaccines. Vaccinated patients register and provide information about how they feel after vaccination. Pregnant patients who receive the RSV vaccine should be encouraged to participate in the V-safe system.

Key Counseling Pearls

- **Ask patients** about potential contraindications to the RSV vaccine because it should not be given to anyone with a history of severe allergic reaction (e.g., anaphylaxis) to any of its components.
- **Inform patients** that common adverse events include injection-site reactions and select systemic events (e.g., fatigue, headache).
- **Educate patients** that in a study the rates of preterm birth were 4.2% in those who received Abrysvo compared with 3.7% in those who did not, but available data are insufficient to establish or exclude a causal relationship between preterm birth and use of the vaccine.
- **Show patients** how to enroll in the V-safe system by visiting the V-safe sign-up page at https://vsafe.cdc.gov/vsafeportal/s/vsafe-register-participant?language=en_US.
- **Patients can also be given** the step-by-step instructions located on CDC's website (https://www.cdc.gov/vaccine-safety-systems/v-safe/access-use.html).

Coadministration With Other Vaccinations

A single 0.5 mL dose of Abrysvo should be given intramuscularly, preferably in the deltoid region of the upper arm. Abrysvo can be given at the same time as other recommended vaccines (e.g., Tdap, influenza, COVID-19). When coadministering vaccines, providers should separate injection sites by 1 inch or more, if possible.

The occurrence of mild to moderate adverse effects (e.g., fever, fatigue) may increase with coadministration of vaccines; however, these effects tend to last only a few days. Pharmacists should make a strong recommendation for these vaccinations to eligible pregnant patients and vaccinate them during the same encounter if the vaccine administration is appropriate (e.g., seasonality for respiratory vaccines, gestational age for Tdap and RSV vaccines, assessment of what the prenatal care provider has already done).

Key Counseling Pearls

- **Inform patients** that RSV vaccine can be coadministered with other vaccines recommended during pregnancy such as Tdap, influenza, and COVID-19 vaccines.
- **Educate patients** that mild to moderate adverse effects (e.g., fever, fatigue) may increase with coadministration of vaccines.

In Conclusion

Pharmacists can play a pivotal role in educating pregnant patients on relevant vaccines, make strong recommendations for their use, and administer the vaccines as appropriate.

Pharmacists are also in a unique position to engage the patient's prenatal care provider and discuss the importance of RSV vaccination for pregnant patients.

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