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The American College of Obstetricians and Gynecologists

Maternal Respiratory Syncytial Virus Vaccination

Practice Advisory | September 2023

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The Society for Maternal-Fetal Medicine endorses this Practice Advisory.

This Practice Advisory was developed by the American College of Obstetricians and Gynecologists with the assistance of Kevin A. Ault, MD, Brenna L. Hughes, MD, and Laura E. Riley, MD.

This Practice Advisory provides guidance for the use of respiratory syncytial virus (RSV) vaccine during pregnancy for the prevention of severe RSV disease in young infants. Pfizer's RSVpreF vaccine (trade name Abrysvo) is the first and only RSV vaccine approved by the U.S. Food and Drug Administration (FDA) and recommended by the Centers for Disease Control and Prevention (CDC) for use during pregnancy to prevent severe illness in young infants.

Summary of Key Recommendations and Points

- The American College of Obstetricians and Gynecologists (ACOG) recommends a single dose of Pfizer's RSV vaccine (Abrysvo) for pregnant individuals between 32 0/7 and 36 6/7 weeks of gestation, using seasonal administration, to prevent RSV lower respiratory tract infection in infants. For most of the United States, RSV season occurs from September through January.

- Clinicians should counsel patients about the maternal RSV vaccine and the monoclonal antibody, nirsevimab, as safe and effective ways to prevent severe LRTI caused by RSV in infants.
- Patient preferences should be considered when determining whether to administer the maternal RSV vaccine or not to administer the maternal RSV vaccine and rely on administration of nirsevimab to the infant after birth.
- Maternal RSV vaccine can be administered at the same time as other vaccines routinely recommended during pregnancy.
- Clinicians should document receipt or declination of maternal RSV vaccination in the patient's medical chart.
- The only RSV vaccine approved for use during pregnancy is Pfizer's bivalent RSVpreF vaccine, Abrysvo.
- GSK's RSV vaccine, Arexvy, is **not approved** for use in pregnancy.

Background

Respiratory syncytial virus is a common respiratory virus that usually causes mild cold-like symptoms. Most people recover in a week or two, but RSV can be a serious illness for some groups including infants and older adults.

Respiratory syncytial virus is one of the most common causes of childhood respiratory illness and results in annual outbreaks of respiratory illnesses in all age groups. An estimated 58,000–80,000 children under age 5 years, most of them infants under age 6 months, are hospitalized each year nationwide because of RSV infection, with some requiring oxygen, intravenous fluids, or mechanical ventilation. Each year, an estimated 100–300 children younger than age 5 years die because of RSV in the United States [1] .

RSV Prevention: Maternal Vaccination

On August 21, 2023, the FDA approved the first RSV vaccine, Abrysvo, for use in pregnant individuals to protect newborns and infants against severe RSV disease in the first 6 months after birth. The FDA approved the vaccine to be administered between 32 and 36 weeks of gestation [2] .

On September 22, 2023, the CDC's Advisory Committee on Immunization Practices (ACIP) voted to recommend a single dose of maternal RSV vaccination for pregnant people at 32 through 36 weeks of gestation, using seasonal administration, to prevent RSV lower respiratory tract infection (LRTI) in infants.

Importantly, while there is a second RSV vaccine from GSK approved for use in older adults, it is not approved for use in pregnancy. Currently the only RSV vaccine approved for use in pregnancy is Pfizer's bivalent RSVpreF vaccine, Abrysvo.

Vaccine Efficacy

Among approximately 3,500 pregnant individuals who received Abrysvo, compared to approximately 3,500 pregnant individuals who received placebo, Abrysvo reduced the risk of severe LRTI in infants by 81.8% within 90 days after birth, and 69.4% within 180 days after birth. In a subgroup of pregnant individuals who were at 32 through 36 weeks of gestation, of whom approximately 1,500 received Abrysvo and 1,500 received placebo, Abrysvo reduced the risk of LRTI in infants by 34.7%, and reduced the risk of severe LRTI by 91.1% within 90 days after birth when compared to placebo. Within 180 days after birth, Abrysvo reduced the risk of LRTI by 57.3% and by 76.5% for severe LRTI, when compared to placebo **2** .

Vaccine Safety

As with other vaccines, the side effects most commonly reported by pregnant individuals who received the RSV vaccine were pain at the injection site, headache, muscle pain, and nausea **2** .

The prescribing information for Abrysvo includes a warning to inform that a numerical imbalance in preterm births in Abrysvo recipients (5.7%) occurred compared to those who received placebo (4.7%). This imbalance was only seen in trial participants residing in low- to middle-income countries. Thus, the available data are insufficient to establish or exclude a causal relationship between preterm birth and Abrysvo. Specifically, the warning informs health care professionals that to mitigate the theoretical risk of preterm birth following administration of RSV vaccine before 32 weeks of gestation, Abrysvo should be administered as indicated in pregnant individuals at 32 through 36 weeks of gestation **2** .

RSV Prevention: Monoclonal Antibody Products

On August 3, 2023, the CDC recommended the use of nirsevimab, a long-acting monoclonal antibody product, for the prevention of RSV in infants and some young children. The CDC recommends one dose of nirsevimab for all infants younger than 8 months, born during—or entering—their first RSV season. For some children between the ages of 8 and 19 months who are at increased risk of severe RSV disease, such as children who are severely immunocompromised, a dose of nirsevimab is recommended in their second season [1].

Nirsevimab has been shown to reduce the risk of both hospitalizations and health care visits for RSV in infants by about 80%. For more information on the use of nirsevimab, see CDC's MMWR.

Another monoclonal antibody product, palivizumab, is available and recommended by the American Academy of Pediatrics (AAP) for some infants under age 24 months at increased risk of hospitalization for RSV infection [3]. For more information on palivizumab, see AAP's Policy Statement.

ACOG Recommendations

The American College of Obstetricians and Gynecologists recommends a single dose of Pfizer's RSV vaccine (Abrysvo) for pregnant individuals between 32 0/7 and 36 6/7 weeks of gestation, using seasonal administration, to prevent RSV LRTI in infants.

For most of the United States, RSV season occurs from September through January. As such, similar to seasonal influenza vaccination, RSV vaccination is recommended for pregnant individuals during the months of September through January. In jurisdictions with seasonality that differs from most of the continental United States (eg, Alaska, jurisdictions with tropical climates), health care professionals should follow state, local, or territorial guidance on timing of administration [4].

Most newborns and infants will not need both maternal vaccination and monoclonal antibody administration. However, because the earliest time of vaccination is 32 weeks, and at least 14 days are needed from the time of maternal vaccination for development and transplacental transfer of maternal antibodies to protect the infant, infants born at less than 34 weeks should receive nirsevimab regardless of maternal vaccination status [4].

In very rare situations, infants born to mothers who were vaccinated at least 14 days before birth may receive nirsevimab based on the clinical judgment of their health care professional. This includes infants who have undergone cardiopulmonary bypass or infants with substantial increased risk for severe RSV disease. Additionally, in situations where the pregnant person may not mount an adequate immune response to vaccination (eg, people with immunocompromising conditions) or have conditions associated with reduced transplacental antibody transfer (eg, people living with HIV infection), administration of the monoclonal antibody may be considered based on the judgment of the health care professional [4].

Implementation Considerations

Adding a new vaccine to the maternal immunization platform does not come without several implementation considerations. The American College of Obstetricians and Gynecologists encourages obstetrician–gynecologists to work with their staff and administrators to develop an implementation strategy that ensures patients have access to all recommended maternal vaccines.

Counseling

Pregnant patients should be counseled about RSV and the risk of infection to their newborns and young infants. Clinicians should explain the difference between RSV, influenza, and COVID-19, and the need for different vaccines to protect against each of these infections.

Clinicians should counsel patients about the benefits of maternal RSV vaccination as a safe and effective way to prevent severe LRTI caused by RSV in infants through age 6 months.

Clinicians should also counsel patients regarding the monoclonal antibody, nirsevimab, as another safe and effective option for newborns if the maternal RSV vaccine is not received during pregnancy. When possible, discussions regarding nirsevimab should include information about whether it will be available to the baby after birth.

Patient preferences should be considered when determining whether to administer the maternal RSV vaccine or not to administer the maternal RSV vaccine and rely on administration of nirsevimab to the infant after birth. Patients should be made aware that if they plan to have their newborn receive nirsevimab, they do not need to receive the maternal RSV vaccine during pregnancy.

See **Box 1** for additional counseling support for clinicians.

Box 1.

Counseling Guide for Clinicians

Maternal RSV Vaccine Benefits

- Newborn is born with immediate protection when vaccination occurs at least 14 days before birth
- Antibodies from maternal vaccination may be more resistant to virus mutation
- Reduces number of vaccines infant receives at birth

Monoclonal Antibody Benefits

- Protection from monoclonal antibody may last longer than maternal vaccination
- Results in antibody development directly to the newborn vs. passive transfer from maternal vaccination

Coadministration with Other Maternal Vaccines

It is critically important that pregnant patients receive all recommended vaccines. Maternal RSV vaccine can be administered at the same time as other vaccines routinely recommended during pregnancy **4** .

Documentation

Documentation of vaccine receipt or declination is an essential component of any immunization program. All vaccines received or declined should be documented in the patient's chart and state immunization information system. As such, clinicians should document receipt or declination of maternal RSV vaccination in the patient's medical chart. Documentation of RSV vaccination or declination is especially critical because of the relationship between maternal RSV vaccination and infant monoclonal antibody administration. Hospitals and pediatric care professionals will need to know the maternal RSV vaccination status in order to counsel patients appropriately about the monoclonal antibody for the newborn.

Please contact clinical@acog.org with any questions.

References

1. Jones JM, Fleming-Dutra KE, Prill MM, Roper LE, Brooks O, Sánchez PJ, et al. Use of nirsevimab for the prevention of respiratory syncytial virus disease among infants and young children: recommendations of the Advisory Committee on Immunization Practices — United States, 2023. MMWR Morb Mortal Wkly Rep 2023;72:920-5. doi: 10.15585/mmwr.mm7234a4
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Topics

Immunization | Infant, newborn | Pregnancy | Respiratory syncytial virus vaccines | Respiratory syncytial virus infections | Respiratory syncytial viruses | Respiratory tract infections | Virus diseases

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