

Clinical Guidelines**Maternal Immunization against Respiratory Syncytial Virus (RSV):
Indonesian Consensus 2025****Muhammad Alamsyah Aziz**

This Executive Summary is derived from the 2025 Consensus on Maternal Immunization against Respiratory Syncytial Virus (RSV), developed by the Indonesian Society of Obstetrics and Gynecology, the Indonesian Pediatric Society, the Indonesian Society of Internal Medicine, and the Indonesian Society of Allergy and Immunology.

Background

Respiratory syncytial virus (RSV) is a major cause of lower respiratory tract infection (LRTI) in infants and young children worldwide. Globally, RSV accounts for more than 33 million episodes of LRTI annually, resulting in approximately 3 million hospitalizations and over 120,000 deaths among children under five years of age.¹ The highest disease burden occurs in infants younger than six months, particularly in low- and middle-income countries, including Indonesia.

In Indonesia and Southeast Asia, RSV contributes to approximately 15–25% of hospitalized LRTI cases, with a consistent seasonal pattern during the rainy season.^{2–4} Limited diagnostic capacity, low awareness, and the absence of effective primary prevention strategies have contributed to the sustained burden of RSV infection. RSV infection during pregnancy has also been reported in pregnant women and may increase the risk of maternal respiratory complications, preterm birth, and severe RSV disease in newborns.⁵

Immunological Rationale for Maternal RSV Immunization

Natural RSV infection does not induce durable protective immunity, and reinfections may occur throughout life due to waning neutralizing antibodies and limited mucosal immune responses.⁶ Young infants, particularly those under six months of age, are at increased risk of severe disease because of immune immaturity.

Maternal RSV immunization aims to provide passive protection to infants through transplacental transfer of RSV-specific immunoglobulin G (IgG). Vaccine-induced antibodies are actively transferred across the placenta via the neonatal Fc receptor, providing protection during the early postnatal period when infants are most vulnerable.⁷

RSV vaccines targeting the prefusion F (pre-F) protein have demonstrated the ability to induce high titers of neutralizing antibodies exceeding those generated by natural infection.⁸ Vaccination administered between 32 and 36 weeks of gestation has been shown to optimize antibody transfer from mother to fetus.⁹

Efficacy of Maternal RSV Vaccination

Phase 3 randomized, double-blind, placebo-controlled trials have demonstrated that the RSV preF vaccine (Abrysvo®) is effective in preventing RSV-associated disease in infants. Vaccine efficacy against severe RSV-associated lower respiratory tract infection was reported to be approximately 81.8% within the first 90 days of life and remained protective through six months of age.¹⁰

Maternal RSV vaccination was associated with substantial reductions in RSV-related hospitalization during the first six months of infancy.¹⁰⁻¹² Real-world data from countries implementing maternal RSV immunization programs have demonstrated comparable effectiveness in reducing RSV-associated hospitalization among infants.¹³

Safety Considerations

Maternal RSV vaccination has demonstrated a favorable safety profile. The most commonly reported adverse events were mild-to-moderate local and systemic reactions, including injection-site pain, fatigue, and myalgia.¹⁴ No significant increase in maternal mortality, infant mortality, or stillbirth was observed in large clinical trials.¹⁰ A numerical imbalance in preterm birth rates was observed in some early trials; however, no causal relationship with vaccination has been established, and no increase in adverse neonatal outcomes was identified.^{11,15} Subsequent surveillance and observational data have not demonstrated a consistent increase in preterm birth following maternal RSV vaccination.¹⁶ Continuous monitoring of adverse events following immunization remains essential.

Maternal Vaccination and Monoclonal Antibodies

In addition to maternal vaccination, monoclonal antibodies such as nirsevimab provide passive immunization for infants and have demonstrated substantial efficacy in reducing RSV-related hospitalization.¹⁷ Current evidence suggests that monoclonal antibodies may be particularly beneficial for high-risk infants or infants born shortly after maternal vaccination. Within this consensus, maternal RSV immunization is recommended as the primary preventive strategy, while monoclonal antibodies may be considered in specific clinical situations.

Recommendations and Conclusion

The 2025 Indonesian consensus recommends maternal RSV immunization at 32–36 weeks of gestation using an RSV prefusion F vaccine approved by the national regulatory authority. Vaccination should be integrated into routine antenatal care and accompanied by appropriate counseling, informed consent, documentation, and surveillance of adverse events.

At present, there is insufficient evidence to support routine revaccination with maternal RSV vaccine in subsequent pregnancies; therefore, routine revaccination cannot yet be recommended.

Maternal RSV immunization represents an evidence-based strategy to reduce RSV-associated morbidity in early infancy and may contribute to lowering hospitalization rates and improving neonatal health outcomes in Indonesia.

REFERENCES

1. Nair H, Nokes DJ, Gessner BD, Dherani M, Madhi SA, Singleton RJ, et al. Global burden of acute lower respiratory infections due to respiratory syncytial virus in young children. *Lancet*. 2010;375(9725):1545-55. doi: 10.1016/S0140-6736(10)60206-1
2. Shi T, McAllister DA, O'Brien KL, Simoes EAF, Madhi SA, Gessner BD, et al. Global, regional, and national disease burden estimates of acute lower respiratory infections due to respiratory syncytial virus in young children in 2015: a systematic review and modelling study. *Lancet*. 2017;390(10098):946-58. doi: 10.1016/S0140-6736(17)30938-8. Epub 2017 Jul 7
3. Suryadevara M, Domachowske JB. Epidemiology and seasonality of childhood respiratory syncytial virus infections in the tropics. *Viruses*. 2021;13(4):696. doi: 10.3390/v13040696
4. Falsey AR, Walsh EE. Respiratory syncytial virus infection in adults. *Clin Microbiol Rev*. 2000;13(3):371-84. doi: 10.1128/CMR.13.3.371.
5. Collins PL, Graham BS. Viral and Host Factors in Human Respiratory Syncytial Virus Pathogenesis. *J Virol*. 2008;82(5):2040-55. doi: 10.1128/JVI.01625-07. Epub 2007 Oct 10. PMID: 17928346; PMCID: PMC2258918.
6. Munoz FM, Piedra PA, Glezen WP. Safety and Immunogenicity of Respiratory Syncytial Virus Purified Fusion Protein-2 Vaccine in Pregnant Women. *Vaccine*. 2003;21(24):3465-7. doi: 10.1016/s0264-410x(03)00352-9.

7. Mclellan JS, Chen M, Joyce MG, Sastry M, Stewart-Jones GBE, Yang Y, et al. Structure-based design of a fusion glycoprotein vaccine for respiratory syncytial virus. *Science*. 2013;342(6158):592-8. doi: 10.1126/science.1243283.
8. Jasset OJ, Jones JM, Chauhan M, et al. Enhanced placental antibody transfer with longer interval between maternal respiratory syncytial virus vaccination and birth. *Am J Obstet Gynecol*. 2025;232(5): 554.e1-15. doi: 10.1016/j.ajog.2024.10.053. Epub 2024 Nov 7.
9. Bebia Z, Reyes O, Jeanfreau R, Kantele A, De Leon RG, García Sánchez M, et al. Safety and Immunogenicity of an Investigational Respiratory Syncytial Virus Vaccine (RSVPref3) in Mothers and their Infants: a Phase 2 Randomized Trial. *J Infect Dis*. 2023;228(3):299–310. doi:10.1093/infdis/jiad024.
10. Dieussaert I, Kim JH, Luik S, et al. RSV prefusion F maternal vaccine preterm birth and other outcomes. *N Engl J Med*. 2024;390(11):1009-21. doi: 10.1056/NEJMoa2305478. PMID: 38477988.
11. Madhi SA, Polack FP, Piedra PA, Munoz FM, Trenholme AA, Simões EAF, et al. Respiratory Syncytial Virus Vaccination during Pregnancy and Effects in Infants. *N Engl J Med*. 2020;383(5):426-39. doi: 10.1056/NEJMoa1908380. PMID: 32726529; PMCID: PMC7299433.
12. Kampmann B, Madhi SA, Munjal I, Simões EAF, Pahud BA, Llapur C, et al. Bivalent prefusion F Vaccine in Pregnancy to Prevent RSV Illness in Infants. *N Engl J Med*. 2023;388(16):1451-64. doi: 10.1056/NEJMoa2216480. Epub 2023 Apr 5. PMID: 37018474
13. Food and Drug Administration. Abrysvo (respiratory syncytial virus vaccine) prescribing information [Internet]. Silver Spring (MD): FDA; 2023 [cited 2026 January 12]. Available from: <https://www.fda.gov>
14. Moro PL, Olson CK, Ellington SR, et al. Post-authorization safety surveillance of RSV pre F vaccine in pregnant persons. *MMWR Morb Mortal Wkly Rep*. 2024;73.
15. Hammitt LL, Dagan R, Yuan Y, Baca Cots M, Bosheva M, Madhi SA, et al. Nirsevimab for prevention of respiratory syncytial virus in healthy late-preterm and term infants. *N Engl J Med*. 2022;386(9):837-46. doi: 10.1056/NEJMoa2110275. PMID: 35235726
16. Drysdale SB, Green CA, Pollard AJ, et al. Nirsevimab efficacy against RSV-associated hospitalization in infants. *N Engl J Med*. 2023 Dec 28;389(26):2425-35. doi: 10.1056/NEJMoa2309189. PMID: 38157500
17. Moline HL, Fleming-Dutra KE, Roper LE, et al. Early estimate of nirsevimab effectiveness for prevention of respiratory syncytial virus-associated hospitalization among infants entering their first RSV season—New Vaccine Surveillance Network, October 2023-February 2024. *MMWR Morb Mortal Wkly Rep*. 2024;73(10):209-14.

Supplementary figure:

Figure 1.







	<h1>RECOMMENDATION</h1>	
<h2>RECOMMENDATION</h2> <p>Physicians and other healthcare providers should recommend respiratory syncytial virus (RSV) immunization and counsel pregnant women on its benefits for maternal health, as well as the passive immunity it provides to newborns.</p> <p style="text-align: center;">Grade A, 1++, High</p>		
<h2>VACCINE TYPE</h2> <ul style="list-style-type: none"> The bivalent prefusion F protein-based vaccine for Respiratory Syncytial Virus (RSVpreF) is recommended for administration to pregnant women at 32–36 weeks of gestation to provide optimal protection against RSV infection in newborns. For RSV prevention in infants, in addition to vaccination, Nirsevimab—a recombinant monoclonal antibody—can be administered, demonstrating up to 98% efficacy in preventing hospitalization. <p>Nirsevimab is recommended for infants under 8 months of age, as well as for children aged 8–19 months who are at high risk.</p> <ul style="list-style-type: none"> Healthcare providers should discuss the relative benefits and limitations of maternal RSVpreF vaccination vs Nirsevimab administration, while taking patient preferences into account when determining whether to immunize the mother during pregnancy or to administer Nirsevimab to the infant. Palivizumab—another recombinant monoclonal antibody, where available—is recommended for infants and children at very high risk (including those born preterm, with chronic lung disease, severe congenital heart disease, or immunocompromising conditions). <p style="text-align: center;">Grade A, 1++, High</p>		
<h2>EFFICACY</h2> <p>The efficacy of the RSVpreF vaccine in pregnant women has been demonstrated in a large-scale, randomized, double-blind, placebo-controlled phase 3 clinical trial.</p> <p>The MATISSE trial (Maternal Immunization Study for Safety and Efficacy) confirmed both the efficacy and safety of RSVpreF vaccination in pregnant women and their infants. The study showed that maternal RSVpreF vaccination significantly reduced the risk of severe lower respiratory tract disease in infants, with an efficacy of 81.8% within 90 days after birth and 69.4% within 180 days.</p> <p style="text-align: center;">Grade A, 1++, High</p>		
<h2>TIMING (IN WEEKS OF PREGNANCY)</h2> <p>The RSVpreF vaccine is recommended for all pregnant women as a single injection at 32–36 weeks of gestation, considering its established safety and efficacy profile.</p> <p style="text-align: center;">Grade A, 1++, High</p>		

Figure 2.

RECOMMENDATION

SAFETY

- Serious adverse events are exceedingly rare and have primarily been associated with a potential increased risk of Guillain-Barré syndrome (GBS) in elderly populations. However, there is insufficient evidence to establish a causal relationship, particularly in pregnancy.
- The RSV vaccine is considered safe for use in pregnant women, with reported adverse effects generally limited to mild symptoms such as injection-site pain, headache, myalgia, and nausea.

Grade B, 2++, moderate

- To date, no safety data are available regarding the use of RSV vaccination in pregnant women with twin or higher-order multiple pregnancies.
- Patients should be informed of the lack of adequate safety evidence, and this information should be incorporated into counseling and shared decision-making when considering RSV vaccination in such cases.

Grade D

INDICATION AND CONTRAINDICATION

- **Indications:** The RSVpreF vaccine is recommended for pregnant women at 32–36 weeks of gestation, including adolescent pregnancies, singleton, and multiple gestations—provided there are no medical contraindications, in order to offer optimal protection for infants against RSV infection.
- **Contraindications:** Vaccination is contraindicated in individuals with a history of severe allergic reactions (e.g., anaphylaxis) or known hypersensitivity to any component of the vaccine.

Grade A, 1++, high

DOSAGE AND ADMINISTRATION

- The RSV vaccine is administered as a single 0.5 mL intramuscular dose by a trained healthcare professional, followed by post-vaccination observation for at least 15–30 minutes to monitor for allergic reactions or acute adverse events.
- Vaccination may be given year-round, timed according to gestational age, to ensure maximal antibody transfer to the fetus.
- RSV vaccines, including RSVpreF, must be stored in a refrigerator at 2°C–8°C (36°F–46°F) in their original packaging and protected from light. Once reconstituted, the vaccine may be kept at room temperature (15°C–30°C or 59°F–86°F) but must be used within 4 hours. The vaccine must **never** be frozen.

Grade A, 1++, high

ANTENATAL CARE (ANC)

- All pregnant women should be screened for RSV immunization during antenatal care (ANC), including assessment of prior RSV vaccination history and any history of allergic reactions.
- Maternal health screening and counseling regarding the benefits and potential risks of vaccination should be conducted before administration, and RSV vaccination can be integrated into routine ANC visits.
- Co-administration of the RSV vaccine with other vaccines such as influenza, hepatitis B, and pneumococcal vaccines is generally safe and effective.
- However, Tdap vaccination should be administered at least two weeks apart, as simultaneous administration with RSV vaccination has been shown to reduce the immunogenicity of Tdap.

Grade A, 1++, high