Clinical Guidelines

Maternal Immunization against Respiratory Syncytial Virus (RSV): Indonesian Consensus 2025

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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 4–7% of 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, at least five weeks prior to delivery, 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 LRTI was 82.4% within the first 90 days of life and remained 69–70% through six months of age.[10,11]

Higher efficacy was observed among infants born to mothers vaccinated at 32–36 weeks of gestation, with a reduction in severe RSV-associated LRTI exceeding 90% during the first three months of life.11 Maternal RSV vaccination was also associated with a 57–68% reduction in RSV-related hospitalizations during the first six months of infancy.[12]

Real-world data from countries that have implemented maternal RSV immunization programs have shown comparable effectiveness, with reductions in RSV-related hospitalizations of approximately 68–74%.[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 small numerical imbalance in preterm birth rates was reported in early trials; however, no causal relationship with vaccination was established, and no increase in adverse neonatal outcomes was observed.[15] Subsequent observational studies did not demonstrate an increased risk of preterm birth following maternal RSV vaccination.[16] Continuous monitoring of adverse events following immunization is recommended.

Maternal Vaccination and Monoclonal Antibodies

In addition to maternal vaccination, monoclonal antibodies such as nirsevimab provide passive immunization for infants and have been shown to reduce RSV-related hospitalizations by more than 80–90%.17-19 Within this consensus, maternal RSV immunization is recommended as the primary preventive strategy, while monoclonal antibodies may be considered in specific situations, including high-risk infants or infants born shortly after maternal vaccination.

Recommendations and Conclusion

The 2025 Indonesian consensus recommends maternal RSV immunization at 32–36 weeks of gestation using an RSV preF 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. Moreover, at present, there is insufficient evidence to support routine revaccination with maternal RSV vaccine in subsequent pregnancies; therefore, 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.

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Supplementary figure:

Figure 1.

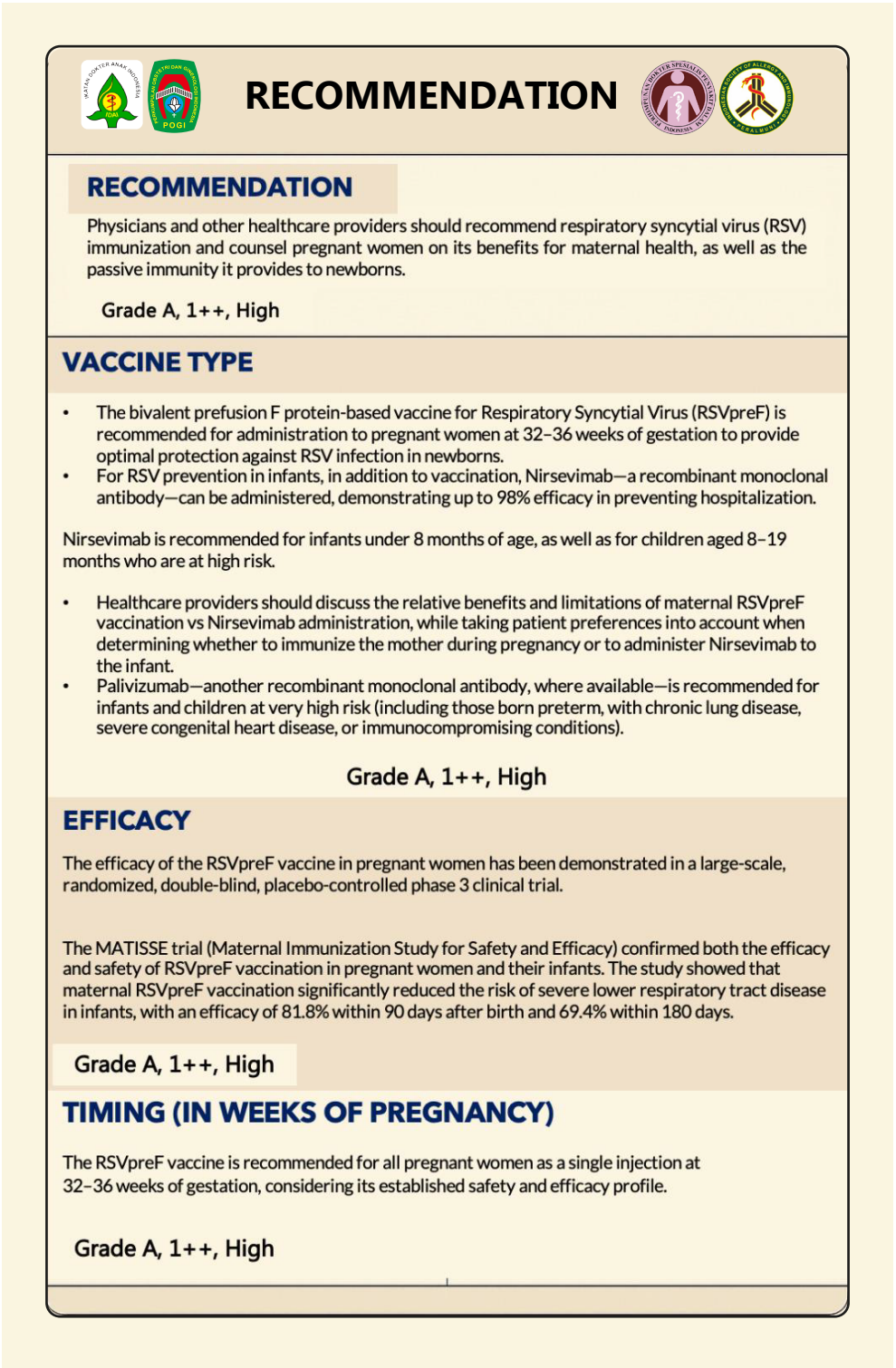
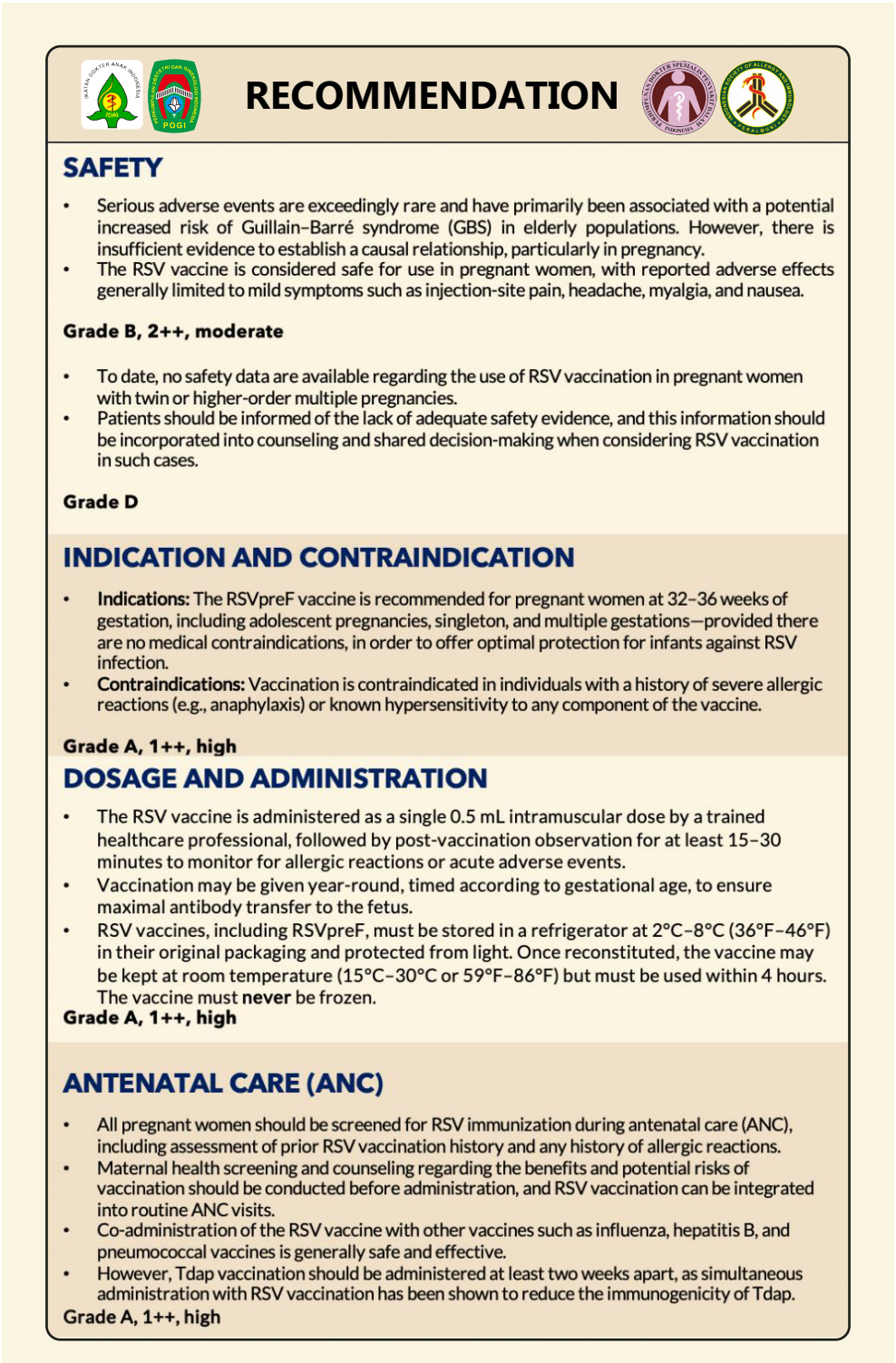


Figure 2.


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