

# Efficacy and safety of RSV vaccines for maternal immunization: A systematic review

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## ABSTRACT

**Introduction:** Respiratory syncytial virus (RSV) is a significant cause of severe respiratory infections in infants, leading to increased hospitalizations. Maternal immunization with RSV vaccines has emerged as a promising strategy to protect newborns during their early vulnerable months and reduce hospital admissions. Currently, RSV vaccination is not administered to pregnant women in Malaysia. The current preventive treatment involves the expensive and limited monoclonal antibody palivizumab, given to infants for direct passive immunity. Treatment of affected infants primarily involves symptomatic care and antivirals like Ribavirin. **Objectives:** This systematic review evaluated the efficacy and safety of RSV vaccines administered during pregnancy in preventing RSV-associated lower respiratory tract infections (LRTIs) in infants. **Materials and Methods:** A comprehensive search of PubMed, Cochrane Library, Embase, and Malaysian Health Technology Assessment Section publications was conducted using keywords like "RSV vaccine", "maternal immunization", "pregnancy", "efficacy" and "safety". Studies were included if they reported on the efficacy or safety of RSV vaccines in pregnant women and their infants. Data extraction and quality assessment were performed using standardized tools and results were synthesized qualitatively and quantitatively where applicable. **Results:** • **Efficacy:** The RSVpreF vaccine (ABRYSVO™) demonstrated significant efficacy in preventing severe RSV-related LRTI in infants, with an efficacy of 69.4% against severe LRTI and 56.8% against RSV hospitalizations within the first 180 days of life (SMFM, 2024) (CDC, 2023). • **Safety:** Common maternal adverse events included injection site pain, headache and muscle pain, which were mild to moderate. Infant adverse outcomes such as low birth weight and jaundice showed no significant increase compared to placebo groups (European Commission, 2023) (FDA, 2023). • **Global Impact:** Maternal immunization has the potential to significantly reduce RSV-related morbidity and mortality, especially in low- and middle-income countries where the burden is highest (Readying the World for Maternal RSV Vaccine, 2019). **Conclusions:** Maternal immunization with the RSVpreF vaccine effectively reduces the incidence of severe RSV-related LRTIs and hospitalizations in infants up to six months old. The safety profile is favourable, supporting its use in maternal immunization programs globally. Further research should monitor the long-term outcomes and evaluate seasonal against universal administration for pregnant women.