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Article review

Maternal vaccination against respiratory syncytial virus infection in infants younger than 6 months: an integrative review

Vacinação materna contra infecção pelo vírus sincicial respiratório em bebês com menos de 6 meses: uma revisão integrativa da literatura

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Abstract

Objective: to synthesize the available scientific evidence on the efficacy of maternal vaccination against RSV infection in infants younger than 6 months. **Methods:** this study is an integrative literature review, designed according to the methodological framework proposed by Whittemore and Knafl[12] and following the PRISMA guidelines (Preferred Reporting Items for Systematic Reviews and Meta-Analyses), ensuring rigor and transparency in the identification, selection, and synthesis of scientific evidence. The literature search was conducted in the electronic databases Scientific Electronic Library Online (SciELO), LILACS Plus Collection and BVS Complete Collection (via the Biblioteca Virtual em Saúde [BVS]). Search strategies were developed in both Portuguese and English using controlled descriptors (*Descritores em Ciências da Saúde* [DeCS] / MeSH terms) and combined through the Boolean operators AND and OR. **Results:** nine scientific articles on maternal RSV vaccination and its effects in infants under 6 months were analysed. The investigation consisted of multicentre observational studies in referral hospitals (Argentina and the United Kingdom) estimating effectiveness against RSV related hospitalization in infants <6 months, phase 3 clinical trials, randomized, double-blind, placebo-controlled trials of the RSVpreF vaccine (Pfizer, MATISSE), a phase 2 and a phase 3 study of RSVPreF3-Mat (GSK), a phase 3 Novavax trial with a nanoparticle antigen and age-structured epidemiological modelling projecting population impact. **Conclusion:** maternal vaccination was effective in reducing hospitalizations and severe RSV associated lower respiratory tract infection in newborns and infants up to 6 months of age, with a favorable safety profile. The RSVpreF vaccine (Pfizer) demonstrated a favorable safety profile with no signals of concern. However, the RSVPreF3-Mat vaccine (GSK) showed a signal of increased preterm birth (6.8% vs 4.9%, p=0.01), leading to early trial termination. Ongoing safety surveillance and post-implementation studies are warranted to refine the magnitude of benefit and to characterize potential risks across diverse populations and settings.
Keywords: Respiratory Syncytial Viruses. Respiratory Syncytial Virus Infections. Vaccination. Pregnant People. Infant, Newborn.

Resumo

Objetivo: sintetizar as evidências científicas disponíveis sobre a eficácia da vacinação materna contra a infecção pelo vírus sincicial respiratório (RSV) em bebês com menos de 6 meses. **Métodos:** trata-se de uma revisão integrativa da literatura, elaborada conforme o referencial metodológico proposto por Whittemore e Knafl e as diretrizes do PRISMA (*Preferred Reporting Items for Systematic Reviews and Meta-Analyses*), assegurando rigor e transparência na identificação, seleção e síntese das evidências científicas. A busca foi realizada nas bases de dados eletrônicas *Scientific Electronic Library Online* (SciELO), Coleção LILACS Plus e Coleção Completa BVS (via Biblioteca Virtual em Saúde [BVS]). As estratégias de busca foram construídas em português e inglês, utilizando descritores controlados (Descritores em Ciências da Saúde [DeCS] / Medical Subject Headings [MeSH]), combinados pelos operadores booleanos AND e OR. **Resultados:** foram analisados nove artigos científicos sobre vacinação materna contra o RSV e seus efeitos em bebês com menos de 6 meses. A investigação incluiu estudos observacionais multicêntricos conduzidos em hospitais de referência (Argentina e Reino Unido) que estimaram a efetividade contra hospitalizações por RSV em lactentes menores de 6 meses; ensaios clínicos fase 3 randomizados, duplo-cegos e controlados por placebo com a vacina RSVpreF (Pfizer, MATISSE); um estudo de fase 2 e um de fase 3 com a vacina RSVPreF3-Mat (GSK); um ensaio fase 3 da Novavax com antígeno nanoparticulado; e modelagem epidemiológica estruturada por idade projetando impacto populacional. **Conclusão:** a vacinação materna mostrou-se eficaz na redução de hospitalizações e de infecções respiratórias graves do trato inferior associadas ao RSV em recém-nascidos e lactentes de até 6 meses de idade, apresentando perfil de segurança favorável. A vacina RSVpreF (Pfizer) demonstrou um perfil de segurança favorável, sem sinais de preocupação. No entanto, a vacina RSVPreF3-Mat (GSK) apresentou um sinal de aumento de partos prematuros (6,8% vs. 4,9%, p=0,01), o que levou à interrupção precoce do ensaio clínico. Recomenda-se a continuidade da vigilância de segurança e de estudos pós-implementação para refinar a magnitude do benefício e caracterizar potenciais riscos em diferentes populações e contextos.
Palavras-chave: Vírus Sinciciais Respiratórios. Infecções por Vírus Respiratório Sincicial. Vacinação. Gestantes. Recém-nascido.

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Introduction

Respiratory syncytial virus (RSV) infection is one of the leading causes of severe acute lower respiratory disease in newborns and infants. RSV, a member of the Pneumoviridae family, is characterized by its high transmissibility and its ability to induce inflammation and obstruction of the lower airways, particularly the bronchioles, resulting in bronchiolitis and pneumonia[1,2]. In neonates, immunological vulnerability is exacerbated by the immaturity of the immune system and by a limited neutralizing antibody response, which favors viral replication and progression to severe clinical outcomes[3,4]. Virtually all children are infected with RSV by the age of two years; however, the highest burden of morbidity and mortality occurs during the first six months of life[5].

RSV is among the main causes of pediatric hospitalization worldwide, accounting for more than 30% of admissions due to respiratory infections in children under one year of age[6]. The severity of illness is closely associated with factors such as prematurity and underlying comorbidities, which increase the risk of complications and the need for ventilatory support[7]. In addition to the direct costs of hospital care and intensive therapy, RSV generates substantial indirect economic losses related to caregiver absenteeism and the overburdening of health services, particularly in low, and middle-income countries, where access to preventive and therapeutic measures remains limited[8,9].

Within this context, maternal immunization has emerged as a preventive strategy to reduce RSV infection in newborns. Vaccination during pregnancy aims to promote the transplacental transfer of maternal IgG antibodies, thereby providing passive immunity to infants during the early weeks of life, when susceptibility to infection is greatest[3,4]. In 2023, the RSVpreF vaccine (Pfizer/Abrysvo) received regulatory approval in the United States, European Union, and other jurisdictions based on phase 3 clinical trial data[15,19], becoming the first and currently only maternal RSV vaccine approved for routine use in pregnant women at gestational weeks 32-36[10,14]. Despite encouraging results, several questions remain to be elucidated, including the duration of conferred immunity, effectiveness across different populations, and potential adverse effects among pregnant women with comorbidities[10,11]. Synthesizing the available evidence is crucial to inform public health policies for incorporating this vaccine into national immunization programs and to guide future investigations on cost-effectiveness and population-level impact, particularly in resource-limited settings[11].

This study aimed to synthesize the available scientific evidence on the efficacy of maternal vaccination against RSV infection in infants under 6 months.

Materials and Methods

This study is an integrative literature review, designed according to the methodological framework proposed by Whittemore and Knafl[12] and following the PRISMA guidelines (Preferred Reporting Items for Systematic Reviews and Meta-Analyses)[13], ensuring rigor and transparency in the identification, selection, and synthesis of scientific evidence. This type of review allows for the integration of findings from diverse studies and provides a comprehensive understanding of the phenomenon under investigation.

The research question was developed using the PICO strategy, defined as follows: P (Population): pregnant women; I (Intervention): vaccination against RSV infection; C (Comparison): unvaccinated women or other preventive measures; O (Outcome): efficacy in preventing bronchioliti. Accordingly, the guiding question was formulated as: "What evidence is available in the scientific literature regarding the efficacy of maternal vaccination against respiratory syncytial virus infection in infants under 6 months?"

The literature search was conducted in the electronic databases Scientific Electronic Library Online (SciELO) and LILACS Plus Collection (via the *Biblioteca Virtual em Saúde* [BVS]). Search strategies were developed in both Portuguese and English using controlled descriptors (*Descritores em Ciências da Saúde* [DeCS] / MeSH terms) and combined through the Boolean operators AND and OR (Chart 1).

Chart 1. Search strategy applied in September 2025, no restriction on publication period.

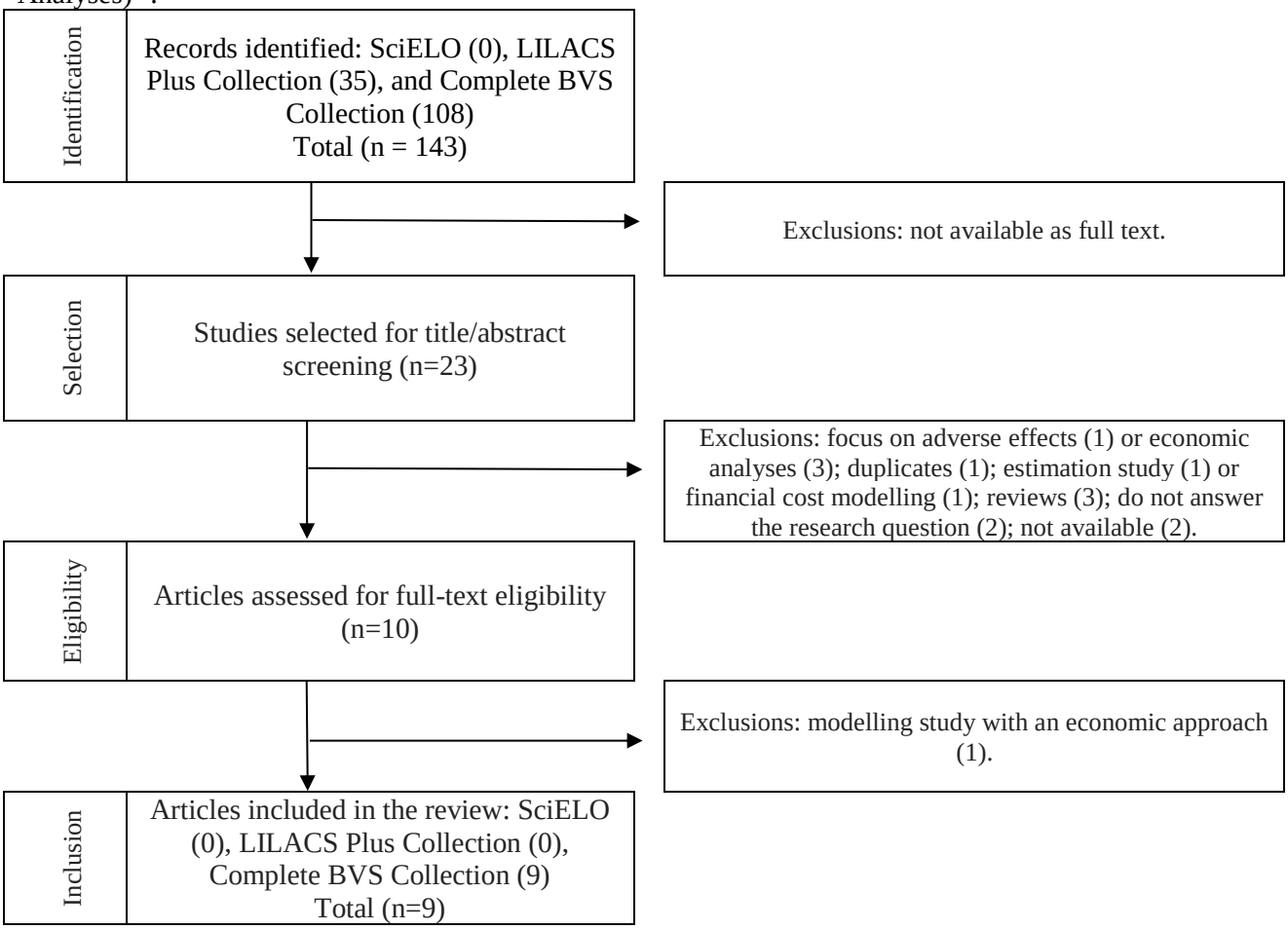
Data-base	Search strategy used	Filters	Results
SciELO	("Vacinação" OR "Imunização" OR "Esquema de Vacinação" OR "Esquemas de Imunização" OR "Cobertura Vacinal" OR "Programa de Imunização") AND ("Bronquiolite" OR "Bronquiolite Viral" OR "Infecção pelo Vírus Sincicial Respiratório") AND ("Recém-nascido" OR "Neonato" OR "Criança Recém-nascida")	Language: English, Portuguese, and Spanish. No restriction on publication period.	0
LILACS Plus Collection	("Vacinação" OR "Imunização" OR "Esquema de Vacinação" OR "Immunization" OR "Vaccination" OR "Programa de Imunização" OR "Immunization Schedule") AND ("Bronquiolite" OR "Bronchiolitis" OR "Infecção pelo Vírus Sincicial Respiratório" OR "Respiratory Syncytial Virus Infection") AND ("Recém-nascido" OR "Neonato" OR "Newborn" OR "Infant, Newborn")	Language: English, Portuguese, and Spanish. No restriction on publication period.	Results: 35. Selected by title and abstract: 2. Selected after full-text reading: 1.
BVS Complete Collection	("Vacinação" OR "Imunização" OR "Esquema de Vacinação" OR "Immunization" OR "Vaccination" OR "Programa de Imunização" OR "Immunization Schedule") AND ("Bronquiolite" OR "Bronchiolitis" OR "Infecção pelo Vírus Sincicial Respiratório" OR "Respiratory Syncytial Virus Infection") AND ("Recém-nascido" OR "Neonato" OR "Newborn" OR "Infant, Newborn") AND ("Gestantes" OR "Pregnant People")	Language: English, Portuguese, and Spanish. No restriction on publication period.	Results: 13. Selected by title and abstract: 13. Selected after full-text reading: 2.

BVS Complete Collection	("Vacinação" OR "Imunização" OR "Esquema de Vacinação" OR "Immunization" OR "Vaccination" OR "Programa de Imunização" OR "Immunization Schedule") AND ("Bronquiolite" OR "Bronchiolitis" OR "Infecção pelo Vírus Sincicial Respiratório" OR "Respiratory Syncytial Virus Infection") AND ("Recém-nascido" OR "Neonato" OR "Newborn" OR "Infant, Newborn")	Main subject: Vaccines against Respiratory Syncytial Virus. Language: English, Portuguese, and Spanish. No restriction on publication period.	Results: 95. Selected by title and abstract: 29. Selected after full-text reading: 8.

Inclusion criteria encompassed original studies addressing vaccination, immunization, or immunoprophylactic strategies aimed at preventing bronchiolitis in newborns, including clinical trials, observational studies, and cohort studies. Eligible publications were required to be peer-reviewed, available in full text, and published in Portuguese, English, or Spanish. Exclusion criteria comprised duplicate studies involving distinct populations, opinion papers, editorials, single case reports, conference abstracts, and review articles.

The search and screening process was performed in three stages: identification of titles and abstracts; full-text reading of eligible studies; and final inclusion based on consensus among reviewers. The selection process followed the PRISMA model (Figure 1).

Figure 1. Search strategy and study selection (Preferred Reporting Items for Systematic Reviews and Meta-Analyses)[13].



Data from the included studies were extracted using a structured instrument containing the following variables: title, author(s), year of publication, country, study design, sample characteristics, type of intervention, outcomes, and main results. The synthesis was carried out through a narrative and descriptive approach, identifying convergences, gaps, and trends concerning the effectiveness of vaccines in preventing bronchiolitis in lactent under 6 months.

As this study is based exclusively on secondary data from published literature, with no direct involvement of human participants, ethical approval by a Research Ethics Committee was not required.

Results

Nine scientific articles on maternal RSV vaccination and its effects in infants were analysed (Chart 2). The investigation consisted of multicentre observational studies in referral hospitals (Argentina and the United Kingdom) estimating effectiveness against RSV related hospitalization in infants <6 months[10,14], phase 3 clinical trials, randomized, double-blind, placebo-controlled trials of the RSVpreF vaccine (Pfizer, MATISSE)[15,17,19], a phase 2 and a phase 3 study of RSVPreF3-Mat (GSK)[18,20], a phase 3 Novavax trial with a nanoparticle antigen[21] and age-structured epidemiological modelling projecting population impact[16].

Settings spanned a middle-income country (Argentina, four pediatric hospitals), a high-income country (United Kingdom, ~30 hospitals), multinational multicentre cohorts in the phase 3 trials (multiple countries), and projections for a national program in Australia. Overall, outcomes focused on infants younger than six months[10,14–16,19–21]. Interventions evaluated were prefusion F (preF) protein–based maternal vaccines: RSVpreF (bivalent, Pfizer) and RSVPreF3-Mat (GSK), administered from late second to third trimester; comparators were placebo (trials) or unvaccinated mothers (observational studies)[10,14–15,18,20].

Primary outcomes reported included RSV related hospitalization (observational)[10,14], RSV-associated lower respiratory tract infection (LRTI) and severe RSV-associated LRTI in infants up to 90 and 180 days (clinical trials)[15,19,21], maternal–neonatal safety and immunogenicity/placental transfer[15,18,20], and projections of infections and hospitalizations averted under varying coverage/efficacy/duration scenarios[16].

In the effectiveness studies, maternal RSVpreF vaccination was associated with a reduction in the risk of RSV related hospitalization among infants < 6 months: in Argentina, high adjusted effectiveness was observed, with fewer days of oxygen therapy and shorter length of stay among

infants born to vaccinated mothers; in the United Kingdom, effectiveness was of moderate-to-high magnitude, and higher when vaccination occurred ≥14 days before delivery[10,14].

In the MATISSE trials (Pfizer, RSVpreF), high efficacy was observed against severe RSV-associated LRTI through 90 and 180 days, with a favorable safety profile and no new safety signals at final analysis, and consistency in the Japanese subgroup, including efficient placental transfer of neutralizing antibodies[15,17,19].

For GSK's RSVPreF3-Mat, the phase 2 study indicated an acceptable safety profile and 10–15-fold increases in neutralizing antibody titers, with efficient placental transfer[20]; the phase 3 study, however, recorded a higher incidence of preterm birth in the vaccine group, leading to early trial termination, despite a lower risk of RSV-associated LRTI versus placebo[18].

For GSK's RSVPreF3-Mat, the phase 2 study indicated an acceptable safety profile and 10-15-fold increases in neutralizing antibody titers, with efficient placental transfer[20]. However, the phase 3 study (RSV MAT-009) was prematurely terminated in February 2022 due to a statistically significant imbalance in preterm birth rates: 6.8% in the vaccine group versus 4.9% in the placebo group (relative risk: 1.37; 95% CI: 1.08-1.74; p=0.01). An imbalance in neonatal mortality was also observed (0.4% vs 0.2%), though not statistically significant. Despite early termination, the vaccine demonstrated efficacy against RSV-associated LRTI: 65.5% against any RSV disease and 69.0% against severe disease. The preterm birth signal was more pronounced in low- and middle-income countries and temporally clustered (April-December 2021), warranting further investigation into potential confounders such as co-administration of other vaccines and concurrent Covid-19 circulation[18].

The Novavax phase 3 trial (nanoparticle-based RSV F protein vaccine with Matrix-M adjuvant) did not meet the pre-specified success criterion for the primary 90-day endpoint of medically significant RSV-associated lower respiratory tract infection (efficacy: 39.4%). However, the vaccine showed efficacy against RSV-related hospitalization (44.4%) and demonstrated good tolerability[21]. In turn, the Australian modelling projected that a continuous maternal vaccination program with 70% coverage and protection up to six months would reduce RSV hospitalizations by 60% (<3 months) and 40% (3–5 months), with a small indirect herd effect[16].

Adverse effects in maternal participants across the RSVpreF (Pfizer) trials were predominantly mild to moderate, including local injection-site reactions and systemic events such as fatigue, headache, and nausea resolving within 2-13 days, with similar adverse event rates in neonates compared to placebo groups[17,19]. All vaccines were administered as single-dose intramuscular injections during pregnancy: RSVpreF at 120 micrograms (60 µg RSV-A and 60 µg RSV-B) between 24-36 weeks gestation[15,17,19] and Novavax at 120 micrograms adsorbed to

aluminum between 28-36 weeks[21]. Optimal antibody transfer occurred when vaccination was administered ≥14 days before delivery, with placental transfer ratios of 1.62-1.90, whereas vaccination <14 days before delivery resulted in substantially lower ratios (0.32-0.67)[15]. The MATISSE trial (RSVpreF) was sponsored by Pfizer[15,17,19] and the Novavax trial by Novavax[21] whereas the observational effectiveness studies from Argentina and the United Kingdom were funded through national health research programs and universities[10,14] independently confirming trial efficacy findings across different funding sources.

Chart 2. Characteristics of the selected studies (n=9).

Author	Objective	Design	Study location and sample	Results
Madhi *et al.*, 2020[21]	To assess the efficacy of the RSV F protein nanoparticle vaccine administered during pregnancy in preventing severe respiratory infection in infants.	Phase 3, randomized, observer-blind, placebo-controlled clinical trial.	4,636 pregnant women and 4,579 newborns in 11 countries (Argentina, Australia, Chile, Mexico, Spain, United Kingdom, USA, among others).	Efficacy: 39.4% up to 90 days and 44.4% for RSV-related hospitalization. The vaccine was well tolerated, although it did not meet the pre-specified success criterion.
Kampmann *et al.*, 2023[19]	To evaluate the efficacy and safety of maternal vaccination with the bivalent RSVpreF vaccine in preventing severe RSV disease in infants.	Phase 3, randomized, double-blind, placebo-controlled clinical trial.	7,358 pregnant women (3,682 vaccine, 3,676 placebo) and 7,128 infants evaluated across 18 countries.	Efficacy: 81.8% up to 90 days and 69.4% up to 180 days for severe RSV disease. No maternal or neonatal safety signals.
Bebia *et al.*, 2023[20]	To evaluate the safety and immunogenicity of the RSVPreF3 vaccine administered during pregnancy and the transplacental transfer of antibodies to newborns.	Phase 2, randomized, double-blind, placebo-controlled clinical trial.	213 healthy pregnant women across multiple countries (USA, Australia, Spain, France, Canada, Panama, South Africa, etc.).	Well tolerated; no severe adverse events. 10–15-fold increase in neutralizing antibody titers and efficient placental transfer (ratio 1.6–1.9).
Nazareno *et al.*, 2024[16]	To simulate the epidemiological impact of maternal RSV vaccination on infections and hospitalizations in infants and the broader Australian population.	Age-structured SEIRS (Susceptible–Exposed–Infectious–Recovered–Susceptible) epidemiological modelling study.	Based on national hospitalization data for children <5 years, calibrated using Australian data.	With standard efficacy and 70% coverage, vaccination would reduce hospitalizations by 60% (<3 months) and 40% (3–5 months), with an overall 4% reduction in RSV incidence.
Otsuki *et al.*, 2024[17]	To evaluate the efficacy and safety of the RSVpreF vaccine in Japanese pregnant women and their infants up to 180 days after birth.	Sub-analysis of the phase 3 MATISSE trial, randomized, double-blind, placebo-controlled.	230 vaccinated and 232 placebo pregnant women; 218 and 216 infants analyzed, respectively, in Japanese hospitals.	Efficacy: 100% up to 90 days and 87.6% up to 180 days. No safety concerns identified.

Dieussaert *et al.*, 2024[18]	To evaluate the efficacy and safety of the maternal RSVPreF3-Mat vaccine and to investigate the potential risk signal for preterm birth.	Phase 3, randomized, double-blind, placebo-controlled clinical trial, terminated early due to safety concerns.	5,328 pregnant women and 5,233 infants in 24 countries across six continents.	Efficacy: 65.5% against RSV disease and 69.0% against severe forms. Increased preterm birth (6.8% vs. 4.9%) and neonatal mortality (0.4% vs. 0.2%) in the vaccine group. Trial terminated early due to safety signal.
Simões *et al.*, 2025[15]	To evaluate the efficacy, safety, and immunogenicity of the bivalent RSVpreF vaccine in pregnant women and their infants up to 6 months of age.	Phase 3, randomized, double-blind, placebo-controlled clinical trial.	7,420 pregnant women in 18 countries; 7,307 infants born (3,660 vaccine, 3,647 placebo).	Efficacy against severe RSV disease: 82.4% up to 90 days and 70.0% up to 180 days. Efficient antibody transfer and no new safety signals.
Williams *et al.*, 2025[14]	To assess the effectiveness of maternal vaccination with the bivalent RSVpreF vaccine in preventing RSV-related hospitalizations in infants in the United Kingdom.	Multicenter, observational, case–control study with test-negative design.	537 mother–infant pairs across 30 hospitals in England and Scotland.	Maternal vaccination reduced RSV hospitalization risk by 58% (95% CI: 28–75) and by 72% (95% CI: 48–85) when administered ≥14 days before delivery.
Gentile *et al.*, 2025[10]	To evaluate the effectiveness of maternal immunization with the RSVpreF vaccine in preventing RSV-associated hospitalizations among infants under 6 months of age in pediatric hospitals in Argentina.	Multicenter, prospective, observational, analytical, nested case–control study (test-negative design).	187 infants (<6 months): 91 RSV-positive cases and 96 RSV-negative controls, across four pediatric referral hospitals in Argentina.	Crude vaccine effectiveness: 68.2%; adjusted effectiveness: 78.7% for preventing RSV-related hospitalizations. Infants of vaccinated mothers had shorter oxygen therapy and hospital stay.

RSV: respiratory syncytial virus.

Discussion

The findings converge toward a clinical benefit of maternal RSV vaccination in infants, with reductions in hospitalizations observed in Argentina[10] and the United Kingdom[14], high efficacy demonstrated in phase 3 clinical trials of Pfizer's RSVpreF vaccine[15,19], consistent results in the Japanese subanalysis[17] and projected population-level impact from the Australian epidemiological modelling[16]. he RSVPreF3-Mat vaccine (GSK) showed moderate efficacy with a signal of increased preterm birth (65.5% against RSV disease, 69.0% against severe disease) but was associated with a statistically significant increase in preterm birth (RR: 1.37; p=0.01), which led to premature termination of the phase 3 trial. This safety signal represents a critical concern requiring thorough investigation and has implications for vaccine platform selection and regulatory approval[18]. The phase 2 RSVPreF3 study demonstrated an acceptable safety profile, strong immunogenic response, and efficient placental antibody transfer[20]. The Novavax nanoparticle vaccine did not meet its pre-specified 90-day primary endpoint, despite showing a reduction in RSV related hospitalizations[21].

Controlled clinical trials with the RSVpreF vaccine (Pfizer) exhibited the highest efficacy rates in preventing severe RSV-associated lower respiratory tract infections in infants—81.8% up to 90 days and 69.4% up to 180 days[15,19]. In contrast, the phase 3 trial of RSVPreF3-Mat (GSK) showed 65.5% efficacy against RSV infection and 69.0% against severe disease[18], indicating a lower performance compared to RSVpreF, though still clinically meaningful.

The Japanese sub analysis of the MATISSE trial confirmed the RSVpreF efficacy pattern, achieving 100% efficacy up to 90 days and 87.6% up to 180 days, with no increase in preterm birth and comparable safety outcomes[17]. This contrasts with GSK's trial, in which maternal vaccination was associated with a 1.37-fold higher risk of preterm delivery, leading to early study termination[18].

From an immunogenicity perspective, RSVPreF3 induced a 10–15-fold rise in neutralizing antibody titers against RSV subtypes A and B, with efficient placental transfer and a gradual decline by the sixth month of life[20]. By comparison, the Novavax nanoparticle-based vaccine elicited a less robust immune response and did not meet the primary efficacy endpoint, although it reduced RSV-related hospitalizations by 44.4%[21].

The maternal RSV vaccines represent distinct technological platforms: RSVpreF is a recombinant protein-based vaccine containing engineered, inactivated RSV prefusion F glycoproteins[15,17,19] while the Novavax vaccine utilizes RSV F protein nanoparticles formulated with Matrix-M adjuvant[21]. All vaccines operate through passive immunization by generating maternal neutralizing IgG antibodies (10-15 fold increase post-vaccination) that transfer transplacentally via FcRn transporters, providing passive immunity to newborns during their vulnerable first six months[15,20,21]. The RSVpreF platform demonstrated a favorable safety profile comparable to placebo[15,17,19] whereas the Novavax platform showed acceptable tolerability but lower immunogenicity and efficacy against medically significant RSV disease at 90 days (39.4%)[21]. These platform differences underscore the importance of vaccine-specific evaluation when introducing maternal RSV vaccination into national immunization programs.

In observational studies, real-world effectiveness was slightly lower than efficacy reported in controlled trials, which is expected in population-based contexts. In Argentina, maternal vaccination reduced RSV-related hospitalizations by 78.7%, with shorter oxygen therapy and hospital stays in infants[10]. In the United Kingdom, overall protection reached 58%, increasing to 72% when the vaccine was administered at least 14 days before delivery[14]. The difference between countries may reflect variations in timing of vaccination, coverage, seasonality, and population composition.

The Australian modelling study complemented these findings, projecting that a national maternal immunization program with 70% coverage would reduce RSV hospitalizations by up to

60% during the first three months of life and by 40% between three and five months, with limited herd effects but a substantial reduction in infant mortality[16].

It is revelant to say that pharmaceltical company economic support may influence the results achieved in theses papers. Differences across studies may be partly explained by sample heterogeneity, geographic variation, vaccine platform, and gestational timing of administration. Observational studies offer greater external validity, yet rely on confounding adjustment and have less control over clinical variables[10,14]. The clinical trials, though methodologically rigorous, involve more selective populations under intensive monitoring, which may overestimate efficacy in real-world settings[15,18,19]. The Australian modelling analysis supports the public health relevance of maternal RSV vaccination but does not replace empirical evidence[16].

Several limitations warrant consideration when interpreting these findings. First, the majority of efficacy data derive from high-income countries with robust health systems; evidence from low- and middle-income countries, where RSV burden is greatest, remains limited. Second, data on vaccine effectiveness in specific vulnerable populations (extremely preterm infants, those with congenital heart disease or chronic lung disease) are scarce. Third, the duration of protection beyond six months of age is uncertain, and the potential impact on RSV epidemiology in subsequent seasons requires investigation. Fourth, the long-term safety profile of maternal RSV vaccination, including potential immune interference with infant vaccines, needs continued surveillance. Finally, the comparative effectiveness of maternal vaccination versus other preventive strategies (such as nirsevimab, a long-acting monoclonal antibody) has not been thoroughly evaluated in head-to-head studies or real-world settings.

Conclusion

Maternal vaccination was effective in reducing hospitalizations and severe RSV associated lower respiratory tract infection in newborns and infants up to 6 months of age. The RSVpreF vaccine (Pfizer) demonstrated a favorable safety profile with no signals of increased preterm birth or other adverse outcomes. However, the RSVPreF3-Mat vaccine (GSK) was associated with a statistically significant increase in preterm birth, leading to trial termination and underscoring the importance of platform-specific safety evaluation. Ongoing safety surveillance and post-implementation studies are warranted to refine the magnitude of benefit and to characterize potential risks across diverse populations and settings.

Future research should address effectiveness in high-burden settings, duration of infant protection, and comparative strategies including monoclonal antibodies and infant immunization.

Author contributions

Conception and design of the research; data collection; analysis and interpretation of the data; writing of the manuscript; critical revision of the manuscript in terms of intellectual content and final presentation: Patricia Mendes de Souza Marino. The author approves the final version of the manuscript and assumes responsibility for all aspects of the work, including ensuring its accuracy and integrity.

Conflict of interest

The author declare no conflicts of interest.

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