Real-world evidence on maternal RSV vaccination uptake, effectiveness, and safety: a systematic review and meta-analysis

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Summary

Background Maternal vaccination against respiratory syncytial virus (RSV)- associated lower respiratory tract infections (LRTI) is available to protect infants during their most vulnerable early months. As the vaccine is rolled out globally, it is important to investigate vaccine uptake, effectiveness, and safety outcomes to inform future research and implementation strategies.

Methods From November 2024 to November 2025, we conducted monthly searches of Ovid databases to identify studies reporting real-world evidence on maternal RSV vaccine uptake, effectiveness, and safety. Studies were screened, relevant data were extracted, and risk-of-bias was assessed by at least two reviewers. Meta-analyses were performed for outcomes with three or more datapoints. Narrative synthesis was performed for other outcomes. PROSPERO registration: CRD42025643585.

Findings Of 5343 studies identified, 21 were included. We estimated an overall uptake of 27.1% (95% confidence interval (CI): 19.1–37.0; I^2: 99.9%; N = 1,308,447 pregnancies in 13 studies) through the seasonal vaccination programme during the 2023/24 RSV season in the United States. The pooled vaccine effectiveness against RSV-associated LRTI hospitalisation in infants younger than six months was 73.6% (95% CI: 66.3–81.0; I^2: 0.0%) based on four studies including 2478 infants. Regarding safety, no significant association was identified between vaccination at 32–35 weeks of pregnancy and preterm birth (OR 0.99 (95% CI: 0.87–1.10); I^2: 0.0%, N = 16,394 pregnancies in 3 studies).

Interpretation Maternal RSV vaccination is effective in preventing RSV-associated LRTI hospitalisation during the first six months of life. More data are required to characterise vaccine effectiveness in narrower age groups. Safety findings support a favourable profile in pregnant individuals. Larger studies, particularly from settings where vaccination is available before 32 weeks' gestation, are required to improve the accuracy for preterm birth estimates, assess other perinatal outcomes, and enhance generalisability. Efforts to increase uptake and reduce disparities will be essential to maximise the benefits of maternal RSV vaccination.

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Research in context

Evidence before this study

Respiratory syncytial virus (RSV) is associated with significant global infant morbidity and mortality. Since 2023, three new immunisation products, RSV F protein (RSVpreF) maternal vaccine and long-acting monoclonal antibodies (nirsevimab and clesrovimab), are available to prevent RSV-associated acute lower respiratory infections (ALRIs), particularly bronchiolitis among young children. Clinical trials among pregnant individuals demonstrated high efficacy against medically attended RSV infection and severe disease in infants. Trials also found a slightly increased but non-significant rate of preterm births within the vaccinated cohort compared to the control groups.

According to the International Vaccine Access Center (IVAC), by January 2026, 31 countries in five World Health Organization (WHO) regions had introduced RSV maternal vaccination as a stand-alone intervention or in combination with monoclonal antibodies. Abrysvo® by Pfizer, which was first rolled out in the United States in 2023, is currently the only RSV vaccine indicated during pregnancy globally. In January 2026, through a PubMed search with the terms ("respiratory syncytial virus" OR RSV) AND (vaccine OR immunisation) AND (uptake OR safety OR effectiveness) AND "systematic review" we identified two relevant publications, with pooled estimates for uptake and effectiveness. No pooled estimates from real-world studies have been developed for safety outcomes. As vaccination programmes expand, systematically analysing the emerging real-world evidence is necessary to monitor the impact of vaccination programmes, support policy makers, healthcare workers and pregnant individuals, and inform future vaccination campaigns.

Added value of this study

Evidence from published articles through October 2025 shows that RSVpreF vaccine has high effectiveness and a favourable safety profile in pregnancy, but early uptake was low and varied by country. We provide a pooled estimate (four studies) for vaccine effectiveness against RSV-associated LRTI hospitalisations in infants during the first six months of life when mothers are vaccinated at least 14 days prior to delivery (limited data for narrower age groups). Our results also contribute a pooled safety estimate for the risk of preterm birth (three studies) and synthesis of evidence for other perinatal outcomes, which indicate that the maternal RSV vaccine has a favourable safety profile for both foetus and mother.

Implications of all the available evidence

Early evidence from the rollout of maternal vaccination against RSV shows it to be an effective tool for protecting infants against severe RSV infection. The findings may inform national immunisation programmes to ensure timely and equitable access to the vaccines for pregnant individuals, with vaccination offered as early as eligibility by national guidelines, given evidence of lower effectiveness of vaccinated individuals within 14 days before delivery. Reassuring findings indicating a favourable safety profile underscore the importance of continued post-licensure monitoring of adverse events and the need for targeted research to further refine risk estimates for preterm birth and other perinatal outcomes, such as hypertension. This systematic review demonstrates that larger real-world studies are needed to develop accurate and granular estimates of outcomes that can address concerns around safety of RSVpreF, potential benefits, and logistical barriers, all of which need to be tackled to optimise uptake and the benefits of RSV maternal vaccination programmes.

Introduction

Respiratory syncytial virus (RSV), one of the most common causes of acute respiratory infections (ARI), contributes substantially to childhood morbidity and health-system burden. Globally, an estimated 33.1 (uncertainty range (UR): 25.4–44.6) million RSV-associated ARI episodes and at least 3 million RSV-related hospitalisations occurred among children under five years of age in 2019.[1] Approximately 40% of RSV-associated ARI hospitalisations (1.4 million; UR: 1.0–2.0) and 50% of in-hospital deaths (13,300; UR: 6800–28,100) occurred in children under six months of age.[1] The high volume of paediatric hospital admissions[2] has a substantial economic impact[3–5] including direct medical[6] and indirect socioeconomic costs. Given this burden, effective preventive strategies providing protection from birth, are essential to reduce hospitalisations, deaths, and strain on health systems.

Passive protection through maternal antibodies has long been recognised as a promising preventive strategy for RSV.[7] A maternal immunisation approach—vaccinating pregnant individuals at an optimal time to generate high levels of RSV-specific antibodies that transfer transplacentally to their unborn

foetuses—offers a means to protect infants during their most vulnerable early months of life.

Maternal RSV vaccine development progressed rapidly in the last decade. A phase 2 trial showed that RSVpreF had a favourable safety profile among pregnant individuals, and their offspring elicited increases in maternal RSV-A and RSV-B neutralising antibody titres (12.7- to 14.9-fold increase) and demonstrated effective placental transfer ratios of approximately 1.6–1.9.[8] Similarly, data from two large phase 3 trials involving over 7300 pregnant individuals across several countries showed high efficacy of maternal immunisation against medically-attended RSV-associated lower respiratory tract infections (LRTI) in vaccine group compared to the placebo group (risk ratio (RR), 0.4 (95% CI: 0.3–0.6)), severe RSV-associated LRTI (RR, 0.3 (95% CI: 0.2–0.4)), and RSV-associated hospitalisation (RR, 0.4 (95% CI: 0.2–0.6)).[9,10] The bivalent RSVpreF, Abrysvo®, is approved for use in pregnancy and administered in late second or third trimester, depending on local guidance.[11]

Clinical trial data demonstrated no major safety concerns. However, premature birth (delivery before 37 weeks of gestation) emerged as a safety signal to monitor in post-licensure studies.[12] Regional differences for preterm outcomes were identified (significant increase of risk in preterm births in South Africa and upper middle-income countries as a group)[13] but overall no significant association was found between RSV maternal vaccine and increased risk of preterm birth.[14]

Maternal RSV vaccination is underway in several countries, it is thus important to synthesise the available evidence on uptake, effectiveness, and safety to support immunisation programmes. A pooled analysis estimated a 68% effectiveness (95% CI: 55–78) for RSV maternal vaccine (three studies)[15] and 30.5% uptake (95% CI: 20.6–42.6) in the early stages of the vaccination programme in the US (three studies).[16] In terms of safety signals, no pooled estimates from real-world studies have been developed. According to data from the International Vaccine Access Center (IVAC), by January 2026 maternal RSV vaccination had been introduced in at least 31 countries.[11] The majority of countries are in Europe (n = 17) and the Americas (n = 9); RSVpreF vaccine has also been introduced in countries in the Western Pacific (n = 2), Eastern Mediterranean (n = 2) and African (n = 1) regions. Availability of RSVpreF vaccine differs across countries in aspects likely to impact uptake. For instance, differences in eligibility criteria (28 gestation weeks in some settings, 32 weeks in others), access through national/publicly funded schemes or private settings only, duration of the vaccination period (seasonal or year-round), availability, and whether maternal immunisation programmes are complemented by infant RSV passive immunisation involving short-acting (e.g. palivizumab) or long-acting monoclonal antibody (e.g. nirsevimab).

This study aims to synthesise the latest available literature and investigate critical knowledge gaps around uptake, real-world effectiveness, and post-licensure safety monitoring of the maternal RSV vaccine in diverse populations.

Methods

Search strategy and selection criteria

This systematic review extends from a previous investigation into a range of RSV immunisation products (protocol CRD42025643585 in PROSPERO).[16,17] From November 2024 to November 2025, we systematically conducted monthly searches of Ovid databases (Medline, Embase, and Global Health databases) to identify studies reporting real-world evidence on maternal RSV vaccine uptake, effectiveness, and safety. The search strategy is available in the Supplementary Materials, p2. Except for pre-prints, no other grey literature was included as the search strategies could not capture other type of publications systematically and due to resource constraints to undertake searches in all relevant sources. Moreover, information is often limited in unpublished reports, conference abstracts, etc to conduct quality assessment and check for potential biases. We followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) reporting guidelines.[18]

Covidence software was used to complete the study screening process.[19] Each study was independently screened by two of five reviewers (DT, SF, BL, LL, CB). We included studies reporting real-world evidence on uptake, effectiveness, and safety in pregnant individuals with documented or self-reported history of maternal RSV vaccination received at any gestational week that met other pre-specified eligibility criteria (Supplementary Materials, p3). If RSVpreF vaccination data among pregnant individuals could not be extracted separately, studies were excluded. Risk-of-bias quality assessments was conducted using Joanna Briggs Institute (JBI) Critical Appraisal Tools.[20] In line with other systematic reviews,[16,17] we considered studies to be at 'low' risk of bias, 'medium' risk of bias and 'high' risk of bias if quality assessment scores were above 75%, 51–74%, and 50% or less, respectively. Disagreements were resolved in discussion with a third reviewer.

Data analysis and statistics

Vaccine uptake (%) was calculated from the number of pregnant individuals who received maternal RSV vaccination prior to delivery over the number of eligible pregnancies or live births, as reported, in a given period. Vaccine effectiveness was defined as the relative reduction in the odds or risk ratio of RSV-associated healthcare utilisation outcomes. Estimates of vaccine effectiveness and corresponding 95% CIs were

extracted for all health outcomes reported. For safety outcomes, we extracted data on prevalence of adverse events following vaccination (number of reports within a vaccinated population) for non-pregnancy specific outcome and estimates of comparisons or associations between vaccinated and unvaccinated groups (p-value, odds ratios, OR; risk ratios, RR; hazard ratios, HR with corresponding confidence intervals) for pregnancy-specific or foetus-related outcomes.

Meta-analyses, using random effects modelling, were conducted to develop pooled estimates when at least three studies reported the same outcome for: (1) uptake in the same country, (2) vaccine effectiveness against specific healthcare utilisation, or (3) specific adverse events post-vaccination. Study heterogeneity was assessed with I^2 statistic: and categorised as: low (<25%), moderate (25–50%), high (>50%). The 'meta' package in the R software (version 4.5.2)[21] was used for meta-analyses.[21] τ^2 Study-specific estimates were weighted according to the inverse of their total variance under the random-effects model. Between-study variance was estimated using restricted maximum likelihood (REML). Vaccine uptake proportions were pooled using the metaprop function. Proportions were logit-transformed prior to analysis (sm = "PLOGIT") and pooled estimates were calculated using inverse-weighting. Summary estimates and 95% confidence intervals were backtransformed to the proportion scale for presentation. Where sufficient data were available, we carried out sensitivity analyses with studies classified as at low risk of bias. Narrative synthesis was employed to describe relationships for factors associated with uptake or safety outcomes for which fewer than three datapoints were available for a country or outcome, respectively. Publication bias was visualised using funnel plots and statistically assessed through Egger's tests where a minimum of 10 studies were included in a random effects model.

Ethics

Ethical approval was not required for this study, as it relied solely on previously published data.

Role of the funding source

There was no funding for this study.

Results

A total of 5,343 studies were identified through database searches. After screening titles and abstracts, 294 full-text studies were assessed for eligibility, 21 studies were included in the review (Fig. 1).[22–42] The study designs and population characteristics of the included studies reporting RSV maternal vaccine uptake, effectiveness, and safety outcomes are available in Table 1, Table 2, and Table 3, respectively. The publication date for the included studies ranged between July 2024 and September 2025. Most studies reported data from the US (n = 14). The other studies provided data from United Kingdom (UK; n = 3), Argentina (n = 3) and France (n = 1). The studies included cross-sectional (n = 9), cohort (n = 7), and case control (n = 6) designs (one study included two designs for different outcomes).[22] According to the risk-of bias assessment (Supplementary Materials, p5 and p6), ten (45%) studies were classified as at low risk of bias, seven at medium risk of bias (32%), and five at high risk of bias (23%).

RSV vaccine uptake

A total of 16 studies reported data on uptake of RSVpreF vaccines by pregnant individuals (Table 1). Of these, 81% (n = 13) studies reported data from the US from the first season when RSVpreF was implemented (2023/24).[22–24,27–32,34,38,40,41] The remaining three studies from the UK and France also reported data from the first season when RSVpreF was implemented in these countries (2024/25).[25,35,37] For the US, a pooled uptake of 27.1% (95% CI: 19.1–37.0, I^2: 100%) was estimated from data of 1,308,447 pregnancies (Fig. 2). The pooled estimate from three studies with self-reported surveys was 39.7% (95% CI: 28.9–51.6, I^2: 100%), while the pooled estimate from ten studies analysing exposure from databases was 24.0% (95% CI: 15.5–35.2, I^2: 94%). In a sensitivity analysis excluding studies with high risk of bias, uptake was 24.5% (95% CI: 14.6–38.0, I^2: 0%) (Supplementary Material, p7). In the UK, the estimates of uptake were 19% from a cross-sectional study in England (N = 911 pregnancies) and 50.4% from a national database in Scotland (N = 2,753,571 pregnancies). In France, an uptake of 27.2% was reported from data of 264,471 pregnancies (Supplementary Material, p8).

Evidence on the relationship between maternal age and uptake of RSVpreF was reported in six studies,[22,24,25,32,37,41] of which five studies reported an increased uptake of maternal vaccination with older age groups or increasing age of the mother using different metrics.[22,25,32,37,41] Three studies reporting univariate analysis found that pregnant individuals vaccinated against RSV tended to be older than those unvaccinated.[32,37,41] However, one study found that maternal age ≥35 years or more, compared to younger age, was not significantly associated with higher RSVpreF vaccine uptake.[24] Results from multivariate models found significant associations: Blauvelt et al. (2025) reported an adjusted odds ratio (aOR) for increasing age interval: 1.09 (95% CI: 1.05–1.12).[22] Gabet et al. (2025) reported that 30–39-year-olds (aOR, 1.16, (95% CI: 1.13–1.18)) and 40–50-year-olds (aOR, 1.08, 95% CI: 1.03–1.13) were more likely to have received the maternal RSV vaccine compared to pregnant individuals in the 25–29 age group. In the same study, pregnant individuals aged <25 years were significantly less likely to be vaccinated against RSV.[25]

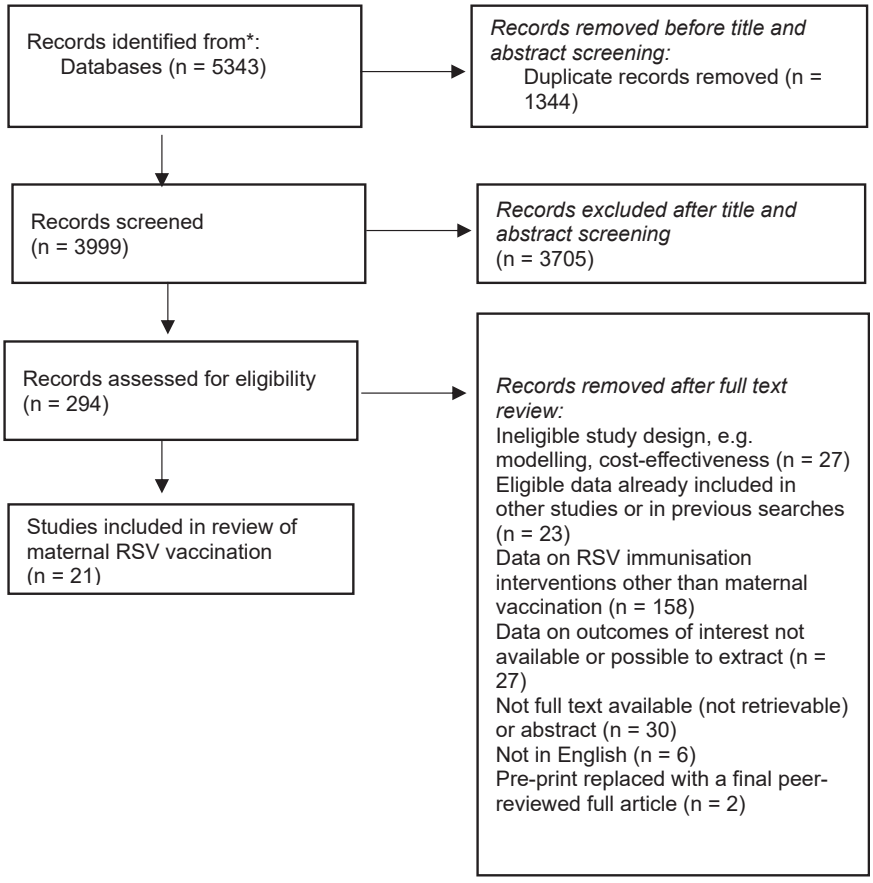


Fig. 1: PRISMA flow chart.

Differences in maternal RSV vaccination uptake by race or ethnic groups, which vary by setting, were reported in four studies.[22,24,31,37] Among studies examining association between ethnic group and RSV maternal vaccine uptake, a study from California (US) found that non-Hispanic ethnicity was associated with a higher RSVpreF vaccine uptake among pregnant individuals compared to Hispanic groups (aOR, 2.36 (95% CI: 1.57–3.55)),[22] while a Minnesota (US) based study did not find a significant association between these two groups (adjusted risk ratio (aRR), 0.98 (95% CI: 0.60–1.59)).[24] In a study from Wisconsin (US) uptake was highest among pregnant individuals who were identified as non-Hispanic Asian or Pacific Islander.[31] Two US studies reported that people identifying as Black had lower RSVpreF uptake compared to Asian (aOR, 0.30, (95% CI: 0.16–0.57))[22] and non-Hispanic White people (aRR, 0.43, (95% CI: 0.22–0.82))[24] in California and Minnesota, respectively. In one hospital study in the UK, Asian (aOR, 0.56, (95% CI: 0.35–0.88)) and Black populations (aOR, 0.52, (95% CI: 0.28–0.95)) were less likely to be vaccinated, compared to White ethnic group.[37]

Type of insurance was also reported as being associated with RSVpreF uptake estimates among pregnant individuals both in the US and Europe.[22,25,31,32,37,41] In the US, an association between private insurance and higher uptake was reported in California (aOR, 2.19 (95% CI: 1.27–3.80)) and in Wisconsin (21.1% *versus* 12.4% in Medicaid or BadgerCare, p-value: <0.0001).[31] Compared to those not vaccinated, the percentage of individuals who received the vaccine during pregnancy and who had private insurance was 42% *versus* 85% (p-value: <0.001)[32] and 6% *versus* 94% (p-value: <0.001)[41] in two studies from New York. In France, despite universal access, there was higher uptake among pregnant individuals in socially advantaged municipalities or with greater health care accessibility and lower uptake was associated with complementary solidarity health insurance status.[25] In the UK, uptake of maternal RSV vaccination was lower among individuals in the most deprived areas (1st quintile), compared to those in the least deprived areas (aOR, 0.28 (95% CI: 0.08–0.81))–a 72% lower odds of maternal vaccination uptake in people from most deprived areas compared to least deprived.[37]

Author	Country	Study setting and data source description	Study period	Study design	Exposure definition	Age pregnant individuals (years)	Study population (denominator)
Blauvelt et al. (2025)	USA	California (1 centre)	Oct 15, 2023–Jan 31, 2024	Retrospective cohort study	Pregnant individuals who received prenatal care and delivered at study facility with had a record of RSV vaccination during pregnancy (32–36 weeks gestation)	Mean (SD) Vaccinated: 35.3 (5.8) Unvaccinated: 33.4 (6.6)	Live births delivered after 32 weeks' gestation
Boundy et al. (2025)	USA	33 states and DC, (CDC WONDER natality data and immunisation records)	Sep 1, 2023–Jan 31, 2024	Cross-sectional	Individuals aged 18–49 years who received RSV vaccination with Abrysvo	Among vaccinated individuals: 18–24 y: 10.9% 25–34 y: 59.2% 35–49 y: 29.9%	Infants born during the study period
Gabet et al. (2025)	France	Nationwide	Sep 15, 2024–Jan 31, 2025	Cross-sectional	Pregnant individuals between 32 and 36 weeks of gestation	Mean (SD) Vaccinated: 30.8 (5.4)	Eligible pregnancies
Hansen et al. (2025)	USA	Washington State, King County (Statewide Immunisation Information System)	Oct 7, 2023–Apr 26, 2024	Modelling study (data, as reported in decision analytical model)	Female residents aged 15–49 who received an RSV vaccine during the study period	No data	Live births during the RSV season
Homo et al. (2025)	USA	Texas, (1 military medical facility)	Oct 16, 2023–Mar 31, 2024	Cross-sectional	Pregnant individuals who gave birth at the study facility whose charts could be reviewed or with an electronic record as documentation of RSV vaccination at least 14 days before delivery	Data available includes unvaccinated mothers who accepted nirsemivab (Median: 30, IQR 8)	Neonates admitted to the mother-baby unit or neonatal intensive care unit, excluding those who died or were transferred before discharge
Hsieh et al. (2025)	USA	TrinetX U.S. Collaborative cohort (22% Northeast, 15% Midwest, 53% South and 10% West)	Sep 1, 2023–Apr 8, 2024	Cross-sectional	Pregnant individuals with a vaccination record between 32 and 36 weeks of gestation	Mean (SD) Vaccinated: 31.2 (5.6) Unvaccinated: 29.1 (6.0)	Deliveries from eligible pregnancies during the study period
Irving et al. (2025)	USA	Various states, National Vaccine Safety Datalink 10 sites	Sep 22, 2023–Mar 31, 2024	Cross-sectional	Pregnant individuals aged 12–55 years with a live birth of 32 weeks gestation or more during the study period with a record on RSV vaccination in electronic health records	Among vaccinated individuals: 12–17 y: 14% (14/118) 18–24 y: 24% (791/3296) 25–34 y: 28% (6550/23,393) 35–49 y: 32% (3242/10,131) 50–55 y: 45% (5/11)	Infants from eligible pregnancies
Kemp et al. (2025)	USA	Wisconsin Immunisation Registry and Office of Vital Records	Oct 1, 2023–Mar 31, 2024	Cross-sectional	Mothers with recorded immunisation information in Wisconsin Immunisation Registry during the study period	Among vaccinated individuals: <20 y: 13.4% 20–24 y: 13.0% 25–29 y: 15.0% 30–34 y: 18.8% 35–39 y: 20.5% 40–44 y: 19.5% >45 y: 13.8%	Live birth occurring in Wisconsin from Oct 2023 to Mar 2024
Lantigua-Martinez et al. (2025)	USA	New York, 3 hospitals	Feb–Mar 2024	Retrospective cohort study	Pregnant patients with information about RSV vaccination in their health records and who delivered at term	Median (IQR) Vaccinated: 34.8 (4.2) Unvaccinated: 30.7 (5.9) p-value: <0.001	Pregnant patients with information about RSV vaccination in their health records and who delivered at term
Litman et al. (2025)	USA	Massachusetts, 1 urban academic centre	Sep 1, 2023–Jan 31, 2024	Retrospective cohort study	Record of RSVpreF administration in a statewide immunisation portal maintained by the Massachusetts Department of Public Health	Median (IQR) Vaccinated: 34.8 (32.1–37.5) Unvaccinated: 33.7 (30.6–36.6)	Live births from individuals eligible to receive RSV vaccination
McLachlan et al. (2025)	UK	Nationwide datasets[a]	Aug 12, 2024–Mar 31, 2025	Population-based cohort	Pregnant individuals in the national SLiOBD dataset with a record of RSV vaccination during pregnancy, including those administered in Scotland and to Scottish residents vaccinated elsewhere	Not available for uptake data, only for mothers of children in effectiveness study	All Scottish infants aged ≤90 days with a record of LRTI hospital admission and tested for RSV

(Table 1 continues on next page)

Author	Country	Study setting and data source description	Study period	Study design	Exposure definition	Age pregnant individuals (years)	Study population (denominator)
(Continued from previous page)							
Razai et al. (2025)	UK	England, tertiary care hospital	Sep 1, 2024–Dec 17, 2024	Cross-sectional	Documented receipt of the bivalent RSV prefusion F (RSVpreF) protein-based (Pfizer) vaccine	Median (IQR) Vaccinated: 35 Unvaccinated: 32 p-value: <0.001	Individuals eligible for vaccination who delivered beyond 20 weeks' gestation and were at 36 weeks or less on Sep 1, 2024
Son et al. (2024)	USA	New York, 1 secondary care centre	Sep 22, 2023–Jan 31, 2024	Cohort	Pregnant individuals who gave birth to singletons at ≥ 32 weeks gestation	Median (IQR) Vaccinated: 35.3 (33.1–38.1) Unvaccinated: 34.6 (31.9–37.3) p-value: <0.001	Singletons born at 32 weeks' gestation or later during the study period
Razzaghi et al. (2024)	USA	USA, Interpanel survey	Mar–Apr 2024	Cross-sectional (self-report internet-based survey)	Individuals who reported receipt of RSV vaccine during pregnancy were considered vaccinated regardless of timing of vaccination	Among vaccinated individuals: 18–24 y: 21.5% 25–34 y: 60.8% 35–49 y: 17.6%	Individuals aged 18–49 years who reported being pregnant at any time since Aug 1, 2023 (until Apr 2024)
Shedlock et al. (2025)	USA	Pennsylvania, one newborn nursery, three clinics academic health system	Nov 27, 2023–Mar 31, 2024	Cross-sectional self-report (survey)	Mother-infant dyad having either received the maternal vaccine (through self-reporting)	Data not available for pregnant individuals	Convenience sample of parents and guardians of infants <8 months in participating newborn nursery or seen for at least 1 well visit at one of three participating primary care
DeSilva et al. (2025)	USA	Minnesota, HealthPartners prenatal care services	Sep–Nov 2023	Cross-sectional self-report (online survey)	Maternal RSV vaccination between 32 and 36 weeks between December 2023 and January 2024	57.9% ≥ 35 years	Pregnant persons ≥18 years who had completed a survey on intention to receive RSV vaccination between 12 and 30 weeks gestation and who had received prenatal care at ≥ 28 weeks at HealthPartners

[a]Scotland, Scottish Linked Pregnancy and Baby Dataset (SLiPBD). National Clinical Data Store (NCDS). RSV positive tests, obtained from Electronic Communication of Surveillance Scotland (ECOSS), and hospital admissions, obtained from Scottish Morbidity Records (SMR01). General Practitioner (GP) records were used to identify infants born in Scotland that were transferred out and therefore lost to follow up. Infant deaths were identified from SLiPBD and from the National Records of Scotland (NRS) deaths dataset.

Table 1: **Characteristics of the included studies reporting uptake of maternal RSV vaccination.**

Four studies reported a higher uptake of RSVpreF vaccines among individuals who had received other vaccines recommended during pregnancy. In France, 96.1% of the cohort of pregnant individuals vaccinated with RSVpreF were vaccinated against pertussis (*versus* 65.5% among unvaccinated with RSVpreF), while coverage against influenza or COVID-19 was 37.2% and 11.1% in those vaccinated with RSVpreF, respectively (*versus* 5.4% and 1.5% in those unvaccinated with RSVpreF).[25] In one US study, coverage of tetanus, diphtheria, and pertussis (Tdap) vaccine among pregnant individuals vaccinated against RSV was 45.5% and for influenza 29.6%. Two studies reported a positive association between uptake of maternal RSV vaccination and other vaccines recommended during pregnancy, such as COVID-19 primary series (aOR, 1.81 (95% CI: 1.17–2.81)),[24] COVID-19 booster (aOR, 5.62 (95% CI: 3.80–8.48)),[22] influenza vaccine (aOR, 8.14 (95% CI: 5.38–12.50)[22] and aOR, 1.43 (95% CI: 1.14–1.79)),[24] Tdap (aOR 6.86 (95% CI: 3.79–13.10)),[22] or having received or planning to receive other recommended vaccines during pregnancies (aOR, 3.25 (95% CI: 1.85–5.71)).[24]

RSV vaccine effectiveness

Five studies reported maternal RSV vaccine effectiveness (Table 2) using test-negative case–control study designs.[26,35,36,39,42] Sample sizes ranged from 187 to 3821 infants and all studies were assessed as low risk of bias, except for one with medium level of risk of bias (Supplementary Tables S5 and S7, p6 and p9). In three studies from Argentina,[26,36,39] the study periods ranged from March or April to September or October 2024. Exposure was defined as having received RSVpreF vaccine between 32.0 and 36.6 weeks of gestation and administered at least 14 days before delivery. In two studies from the UK,[35,42] study periods ranged from August (Scotland) or September (England) 2024 to January 2025 and vaccination was offered as close as possible after reaching 28 weeks of gestation. Exposure was defined as maternal RSVpreF vaccine receipt before delivery. Nirsevimab was not available during the study periods in either setting. The use of palivizumab for the prevention of severe RSV-associated disease was not reported in the studies.

All five studies showed that vaccination >14 days before birth conferred protection against

Authors	Country	Study setting	Study period	Study design	Exposure definition	Study population characteristics
Gentile et al. (2025)	Argentina	4 paediatric referral hospitals (Buenos Aires, Rosario, Posadas)	Mar 15, 2024–Oct 31, 2024 (RSV season)	Test-negative case–control	RSVpreF vaccine between 32.0 and 36.6 weeks of gestation, from the date of last menstrual period, and administered at least 14 days before delivery	Infants born after March 15, 2024, who were hospitalised for ALRI at any of the 4 centres and underwent RT-PCR testing for respiratory viruses upon admission 75.8% of cases and 45.8% of controls were under 3 months of age
Perez Marc et al. (2025)	Argentina	12 hospitals	Apr 1, 2024–Sep 30, 2024 (RSV season)	Test-negative case–control	RSVpreF vaccine received between 32.0 and 36.6 weeks of gestation and at least 14 days before delivery	Infants (<6 months) who were hospitalised with LRTI during the study period and tested for RSV using PCR or indirect immunofluorescence VE analysed by < 3 months and < 6 months
Scruzzi et al. (2025)	Argentina	Cordoba, 4 hospitals	Mar 31, 2024–Oct 31, 2024 (RSV season)	Test-negative case–control	Maternal RSV vaccination between 32 and 36 weeks of gestation at least 14 days before birth	Children born between 31 March and 31 October 2024 with a record of hospitalisation due to laboratory-confirmed RSV infection (PCR, direct immunofluorescence or rapid test) 96.6% of cases were under 4 months of age (62.2% ≤ 2 months and 34.4% > 2 to ≤4 months) and 97% of controls were under 4 months of age (61.9% ≤ 2 months and 35.1% > 2 to ≤4 months) at the time of consultation
McLachlan et al. (2025)	UK	Nationwide datasets[b]	Aug 12, 2024–Mar 31, 2025 (RSV season)	Test-negative case–control[a]	Pregnant individuals in the national SLiOBD dataset with a record of RSV vaccination during pregnancy, including those administered in Scotland and to Scottish residents vaccinated elsewhere	All Scottish infants aged ≤90 days with a record of LRTI hospital admission and tested for RSV
Williams et al. (2025)	UK	30 hospitals, across England and Scotland	Sep 30, 2024–Jan 20, 2025 (RSV season)	Prospective, nested test-negative case–control in multicentre cohort study	Pregnant individuals with information about RSVpreF (and pertussis) vaccination, regardless of the timing of vaccination in relation to birth	Infants aged 0–5 months admitted to 30 hospital sites across the UK with a clinician-assigned diagnosis of bronchiolitis, LRTI or first episode of wheeze and tested for RSV Median (IQR) age in months at admission of cases was 1.63 (0.94–2.26) for cases and 1.41 (0.77–2.03) for controls

[a]Study reports additional analysis with population-based cohort but data from case–control were extracted for meta-analysis. [b]Scotland, Scottish Linked Pregnancy and Baby Dataset (SLiPBD). National Clinical Data Store (NCDS). RSV positive tests, obtained from Electronic Communication of Surveillance Scotland (ECOSS), and hospital admissions, obtained from Scottish Morbidity Records (SMR01). General Practitioner (GP) records were used to identify infants born in Scotland that were transferred out and therefore lost to follow up. Infant deaths were identified from SLiPBD and from the National Records of Scotland (NRS) deaths dataset.

Table 2: **Characteristics of studies reporting effectiveness of maternal RSV vaccination.**

RSV-associated LRTI hospitalisation in infants. Vaccine effectiveness against RSV-associated LRTI hospitalisation (confirmed by polymerase chain reaction (PCR) or nucleic acid amplification test (NAAT)) in infants younger than six months of age pooled from four studies was 73.6% (95% CI: 66.3–81.0, I^2: 0.0%) as shown in Fig. 3. Participant-level data were extracted from four studies, comprising 2478 pregnancies. Vaccine effectiveness in infants under six months old pooled from three studies in Argentina was 74.0% (95% CI: 66.0–82.0; I^2: 0.0%) (Supplementary Figure S1, p7). Sensitivity analysis with only studies at low risk of bias showed similar results (73.4%; 95% CI: 63.5–83.2) (Supplementary Figure S2, p7). Estimates of vaccine effectiveness against RSV-associated LRTI hospitalisation among infants younger than 3 months were available in two studies, one from Argentina: 78.6% (95% CI: 62.1–87.9) and from Scotland 82.9% (95% CI: 75.9–87.8) (Supplementary Materials, p9).

Effectiveness of vaccine received less than 14 days before delivery was reported in two studies from the UK.[35,42] In one study, the adjusted effectiveness against RSV-associated LRTI hospitalisation among infants younger than six months was higher when mothers vaccinated less than 14 days before delivery were excluded from analysis (58% (95% CI: 28–75) *versus* 72% (95% CI: 48–85)).[42] In the second study, the estimate of vaccine effectiveness against RSV-associated hospitalisation in infants younger than three months born to mothers vaccinated less than 14 days before delivery was 29.6% (95% CI: –19.6–56.6).[35]

Effectiveness of maternal RSV vaccination against clinical outcomes other than hospitalisation could not be pooled due to limited data. One study reported that effectiveness against RSV-associated severe LRTI (respiratory failure, hypoxia, ICU-level care, or altered consciousness) leading to hospitalisation was 76.9% (95% CI: 45.0–90.3) in infants under 6 months.[36] One

Authors	Country	Study setting	Study period	Study design	Exposure definition	Study population	Outcomes reported
Blauvelt et al. (2025)	USA	California (1 centre)	Oct 15, 2023–Jan 31, 2024	Nested case–control within retrospective cohort study for pre-term outcome	Pregnant individuals who received prenatal care and delivered at study facility with had a record of RSV vaccination during pregnancy	Pregnant individuals and live births delivered after 32 weeks' gestation	Pregnancy-specific and foetus-related
Hsieh et al. (2025)	USA	TrinetX U.S. Collaborative cohort[a]	Sep 1, 2023–Apr 8, 2024	Cross-sectional with propensity Score[b]	Pregnant individuals with a vaccination record between 32 and 36 weeks of gestation	Births from eligible pregnancies during the study period	Pregnancy specific
Li et al. (2025)	USA	VAERS[c] reports	May 3, 2023, and December 27, 2024	Cross-sectional	Terms associated with adverse effects submitted by anyone reporting having received RSVpreF	Any report in VAERS during the study period	Percentages for non pregnancy-specific, pregnancy-specific, and foetus-related among vaccinated individuals
Litman et al. (2025)	USA	Massachusetts, urban academic centre	Sep 1, 2023–Jan 31, 2024	Retrospective cohort	Record of RSVpreF administration in a statewide immunisation portal maintained by the Massachusetts Department of Public Health	Pregnant individuals and live births from individuals eligible to receive RSV vaccination	Pregnancy-specific
Razai et al. (2025)	UK	England, tertiary care hospital	Sep 1, 2024–Dec 17, 2024	Cross-sectional	Documented receipt of the RSVpreF (Pfizer) vaccine	Individuals eligible for vaccination who delivered beyond 20 weeks' gestation and were at 36 weeks or less on Sep 1, 2024	Pregnancy-specific and foetus-related
Son et al. (2024)	USA	New York, secondary care	Sep 22, 2023–Jan 31, 2024	Cohort	Pregnant individuals who gave birth to singletons at $\geq$ 32 weeks gestation	Pregnant individuals and singletons born at 32 weeks' gestation or later during the study period	Pregnancy-specific

[a]22% Northeast, 15% Midwest, 53% South and 10% West. [b]Maternal age, demographics, health utilisation, comorbidities, medications, assisted reproductive technology, multigestation, multiparity, history of pregnancy complications, social factors, BMI). [c]Vaccine Adverse Event Reporting System (VAERS).

Table 3: **Characteristics of studies reporting data on safety events after maternal RSV vaccination.**

study reported an estimated effectiveness of 71% (95% CI: 47–85) against RSV-associated ALRI requiring high-flow nasal cannulae support,[42] and 64% (95% CI: 1–87) effectiveness against RSV-associated paediatric intensive care admission.[42] One study reported vaccine effectiveness against RSV-associated hospitalisation among children born prematurely (<37 weeks of gestation) of 82% (95% CI: 52.2–97.6).[35] Owing to the sample size, some estimates above had wide confidence intervals (Supplementary Table S6, p8).

Two studies reported on the length of clinical outcomes associated with severity. One study found that children with RSV whose mothers received RSVpreF vaccination (12 cases) compared to no history of

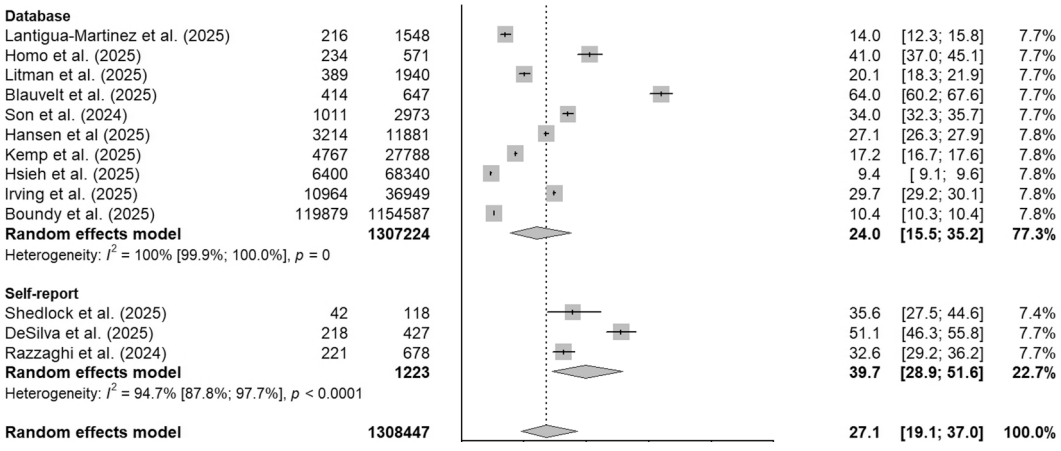


Fig. 2: Uptake of maternal RSV vaccination in the United States during the 2023/24 RSV season, by type of source 95% CI = 95% confidence interval (shown with error bars).

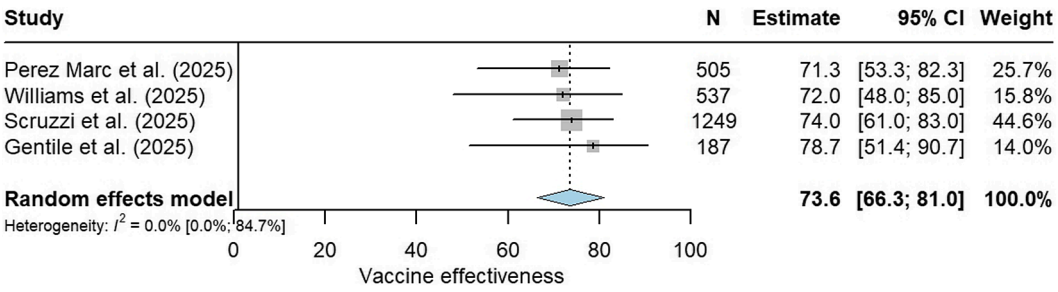


Fig. 3: Maternal vaccine effectiveness against RSV-associated LRTI hospitalisation in infants in included studies during the 2024/25 RSV season, N = total number of pregnancies or live-births considered, 95% CI = 95% confidence interval (shown with error bars).

maternal RSV vaccination (79 cases) had statistically shorter duration of oxygen therapy (4 *versus* 7 days) and hospital stay (5 *versus* 8 days).[26] Another study did not find a statistically significant difference between infants born to vaccinated (median: 4 days; IQR: 1–6 days) *versus* non-vaccinated mothers (median: 3 days; IQR: 2–5 days).[42]

RSV vaccine safety

We included six studies reporting adverse events after maternal RSV vaccination (Table 3).[22,29,33,34,37,41] Five studies included reports of adverse events post RSVpreF vaccination received after reaching 32 weeks' gestation in the US. One study reported data from individuals vaccinated after 28 weeks of gestation in England, UK. Three were cohort studies, one of which included a nested case–control study for preterm outcomes, and three were of cross-sectional design. Four studies (67%) were assessed as low risk of bias (Supplementary Table S5, p6). Five studies reported on adverse events after recorded maternal RSV vaccinations: four from single centres,[22,34,37,41] and one from a multi-centre surveillance dataset.[29] One study analysed 237 diagnoses reported data from the Vaccine Adverse Event Reporting System (VAERS)[33] a passive surveillance system to which anyone can report events post-vaccination, where data from unvaccinated pregnant individuals are not available to enable comparisons.

Regarding non-pregnancy-specific adverse events after vaccination with RSVpreF among pregnant individuals, one study reported: injection site reaction (including swelling, warmth, pain, induration, pruritus, rash, urticaria, vesicles, cellulitis, oedema) in 8.9% (21 of 237) reports received by VAERS during the 2023/24 RSV season in the US, followed by pain (including headache, myalgia, sciatica, arthralgia, chest pain, abdominal pain) in 7.2% (17 of 237) reports, and pyrexia in 5.9% (14 out of 237) reports.[33]

Estimates comparing pregnancy-specific and foetus-related outcomes between vaccinated *versus* unvaccinated individuals were available in five studies.[22,29,34,37,41] For hypertensive disorders of pregnancy (HDP), two studies, one from England (vaccinated: 13/173, unvaccinated: 45/738 p = 0.067)[37] and one from the US found proportions between groups comparable (vaccinated: 99/144, unvaccinated: 71/233 p = 0.08).[22,37] Studies also reported on associations: a study from the US found RSVpreF was not associated with a statistically significant change in risk between groups (aRR 0.97; 95% CI: 0.91–1.03) for the combined outcome of gestational trophoblastic neoplasia (GTN), preeclampsia or eclampsia in one study.[29] In another study, risk of hypertensive disorders of pregnancy was higher among vaccinated individuals (hazard ratio (HR) 1.43; 95% CI: 1.16–1.77), but when ORs were calculated, no association was identified (aOR 1.10; 95% CI: 0.90–1.35).[41] The study from England estimated an aOR 1.29 (95% CI: 0.63–.2.53) for hypertension in pregnancy among vaccinated individuals.[37] For stillbirth, one study from England found no significant difference between vaccinated and unvaccinated groups (0/173 *versus* 8/738; p = 0.320).[37] Although a low number of stillbirth pregnancy outcomes were reported in a study from the US, authors found no association between exposure to maternal RSV vaccination and stillbirth (OR 1.29; 95% CI: 0.17–7.82) (Supplementary Table S8, p10). For preterm births, four studies reported relevant data.[22,29,37,41] In England, the proportion of infants born premature (<37 gestational weeks) to eligible for vaccination at 28 weeks of gestation (10% of 173 individuals) was comparable to the proportion among unvaccinated mothers (9.6% of 738, p = 0.980).[37] Adjusted odd ratios from two studies and one adjusted risk ratio from one study reporting outcomes of 16,394 pregnancies in the US with vaccination available from 32 weeks of gestation[22,29,41] were pooled for a meta-estimate of 0.99 (95% CI: 0.87–1.10 I^2: 0.0%) (Fig. 4).

Risk of publication bias

Visual inspection of the funnel plot and Egger's regression test suggested evidence of funnel plot asymmetry (t = 2.69, p = 0.021) for studies reporting vaccine uptake (Supplementary Material, p11 and p12). The trim-and-fill procedure imputed seven potentially

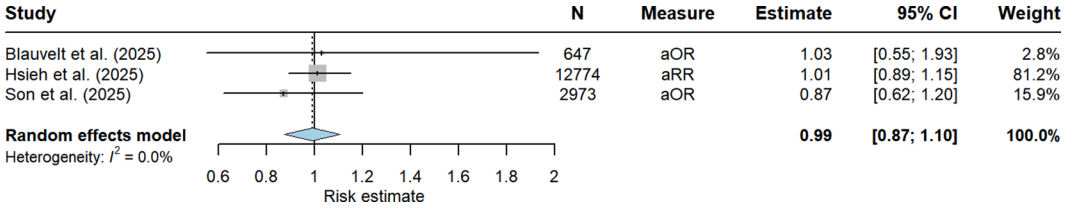


Fig. 4: Risk of premature birth between vaccinated against RSV and non-vaccinated pregnant individuals in included studies during the 2023/24 RSV season. N = total number of pregnancies or live-births considered, 95% CI = 95% confidence interval (shown with error bars).

missing studies on the left side of the funnel plot, indicating that studies reporting lower RSV vaccine uptake may be underrepresented. However, interpretation should be cautious given the substantial between-study heterogeneity (I^2 = 100%), which may contribute to asymmetry independently of publication bias.

Discussion

Our systematic review synthesises real-world evidence indicating high effectiveness of RSV maternal vaccination in reducing RSV-associated LRTI hospitalisations among infants and suggesting a favourable vaccine safety profile. However, our findings also show that uptake of maternal RSV vaccination during the first seasons of implementation was low.

The lowest uptake estimates were reported from countries with hybrid immunisation programmes (maternal vaccine and infant long-acting monoclonal antibodies), such as the US and France. Our pooled estimate, based on data covering over 1 million pregnancies in the US, showed uptake of 27.1% with 95% CI: 19.1%–37.0% during the 2023/24 RSV season, which is similar to the estimate in a previously published meta-analysis.[16] The pooled estimate should be interpreted with caution as heterogeneity is high and reflects an average across diverse settings in the US. Yet, the lower confidence interval aligns with the CDC's national estimate based on Vaccine Safety Datalink of 17% during the same season, while the upper confidence interval aligns with 38.0% achieved during the period September to December 2024.[43] Uptake of maternal RSV vaccination during the first season of programme implementation in France (27% in 2024/25 RSV season) was in the same range as in the US. Of note, in France the demand for nirsevimab was higher than expected (~80% of infants born).[44] Estimates of uptake in countries with RSV maternal vaccination as a single strategy also suggest there are several challenges that need to be addressed to achieve optimum coverage. For instance, Argentina achieved 62% coverage during the first year of their maternal RSV vaccination programme.[45] In the UK, monthly uptake from introduction in September 2024[46] has remained under 65%, with the highest coverage of 57.8% among individuals giving birth in August 2025 in England[47] and 61.5% among live births in October 2025 in Scotland.[48] Further quantitative and qualitative studies to understand the reasons that influence uptake, including attitudes towards different RSV immunisation options,[49] and strategies to increase public confidence are needed.

Despite differences in national health systems in North America and Europe, studies included in this review point towards lower uptake of maternal RSV vaccine among individuals with limited access to health care, as well as in people of specific ethnic groups. Differences in uptake of RSV vaccination according to type of insurance, residence in deprived areas, and ethnicity were previously reported[16] and are consistent with evidence from other countries[50] and for other maternal vaccines.[51] We identified studies reporting higher uptake as maternal age increased. The role of age should be further investigated as generalisability of this finding may be influenced by context-specific considerations (e.g. choice of RSV infant immunisation product) and the relatively small sample sizes of the studies included.

Our findings indicate that maternal RSV vaccination is an effective intervention to protect infants against RSV-associated LRTI requiring hospitalisation during the most vulnerable months of life. The pooled estimate of 74% in infants under six months aligns with the results from clinical trials which showed efficacy ~70% in preventing severe (medically-attended) RSV-associated disease in infants under six months age.[52,53] Our pooled estimate, based on four studies, is higher than a previous meta-analysis of three studies,[15] and recent estimates from the US of 70% (95% CI: 37–86%)[54] and from France (50%; 95% CI: 45–55%)[55] in children less than six months of age. Considering the uncertainty levels of available estimates, reflected in confidence intervals, future meta-analyses with data from diverse settings will help refine estimates, increase generalisability and explore heterogeneity across populations.

The data synthesised in our review underscores the importance of ensuring pregnant individuals can access RSVpreF vaccination well before their estimated due date. Effectiveness is reduced when the vaccine is received less than 14 days before delivery, likely because insufficient time is available for transplacental transfer of protective antibodies. The WHO recommends

administering the vaccine more than 2 weeks prior to delivery, while not specifying an upper limit except in cases where the mother is already in active labour.[56]

Our review demonstrated that the safety profile of the RSV maternal vaccine is favourable. Preterm birth was one of the safety signals noted during clinical trials which included pregnant people between 24 and 36 weeks' gestation, though there were no significant differences between vaccinated and placebo groups.[53] Our meta-analysis indicated no significant association between maternal RSV vaccination and preterm birth. Notably, a recent estimate using data from over 13,000 matched pairs in the US Vaccine Safety Datalink (VSD) project,[57] lies within the range of our meta-estimate. Although current real-world evidence does not support an increased risk of preterm birth following maternal RSV vaccination and heterogeneity was negligible in our meta-analysis, all the studies were from the US where eligible individuals are vaccinated after 32 weeks of gestation, and the sample size of the included studies warrants caution during interpretation. Comparative studies, such as recently published with data from France,[55,58] evaluating the impact of RSVpreF by different gestational vaccination windows will be important to guide policy on the interval between vaccination and estimated delivery date to maximise effectiveness without compromising maternal or foetal safety. While most countries in the Americas recommend RSVpreF for pregnant persons at 32–36 weeks gestational age,[14] WHO's Strategic Advisory Group of Experts on Immunisation (SAGE)[56] and other advisory groups such as in the UK[46] or Australia[59] advise immunisation as soon as possible after 28 weeks' gestation.

Our review identified several knowledge gaps. Firstly, effectiveness data against RSV-associated LRTI hospitalisations in infants by narrow age intervals (≤3 months, 3–6 months) and beyond 6 months of age are needed for more granular assessment. Secondly, we did not identify sufficient reports on effectiveness data by gestational week at vaccination (e.g. 32–≤34 *versus* >34 weeks) and days prior to delivery (e.g. ≥28 days *versus* 14–27 days *versus* < 14 days) to conduct meta-analyses, nor in specific populations such as high-risk pregnancies or those with reduced/impaired transplacental antibody transfer (HIV infection and placental malaria). There is also paucity of data on effectiveness against severe outcomes and medically attended (not hospitalised) infections. The data on factors associated with uptake highlight the need for further research, including consideration of long-acting monoclonal antibody in addition to maternal vaccine at certain gestational ages and provision of monoclonal antibody to babies who were born within 14 days of maternal vaccination. Finally, to provide further reassurance, continuous monitoring of the safety profile of maternal RSV vaccination products is needed including preterm birth and other perinatal outcomes. For hypertensive disorders of pregnancies, studies employed different analytical approaches and effect measures that were not directly comparable for meta-analysis. Studies reporting logistic regression models did not identify a statistically significant association. Conversely, an analysis using a time-to-event approach did report a significantly increased hazard. More recently, a small but statistically significant increased risk (adjusted risk ratio of 1.13 95% CI: 1.07–1.19) among vaccinated individuals was also reported from a study in the US using a log-binomial regression model.[57] The inconsistent findings point towards the need for longer-term surveillance and careful examination of the model to explore the association. Yet, studies consistently conclude that the estimated risks identified to-date do not outweigh the overall favourable safety profile of the vaccine. As maternal RSV immunisation programmes continue to be introduced, data from different vaccine administration strategies (year-round *versus* seasonality, different suggested gestational age at vaccination), ethnic populations, and among high-risk pregnancies will be useful to develop operational recommendations, risk communication and to continue building confidence.

There are several limitations in our study, some of which are inherent to all meta-analyses using data from observational studies. The estimates provided are based on studies with different designs and follow-up duration, varied sample sizes and in a limited number of countries. Considering that overall uptake as a single metric can obscure trends over time or seasons, future reviews should conduct seasonal and year-round subgroup analyses. Our study applied strict inclusion criteria and assessed risk of bias to ensure the most comparable data were pooled. While most studies were classified as low risk of bias, misclassification of vaccination status or outcomes cannot be ruled out. Most of our meta-analysis models included fewer than 10 studies which did not allow us to test for potential publication bias. For risk of preterm birth, we pooled adjusted odds ratios or risk ratios, as available, but residual confounding despite adjustment can influence estimates. Heterogeneity in vaccine effectiveness and preterm risk was low (I^2 <25%), yet high in the pooled estimate for uptake. Evidence for subpopulations such as high-risk pregnancies was not identified. We limited the scope of the search to full articles, peer-reviewed or pre-print, which may introduce bias through underrepresentation of relevant unpublished studies or non-academic country-specific reports. We only estimate uptake of maternal RSV vaccination and not infant immunisation coverage, which in some settings may include long-acting monoclonal antibodies.

This systematic review demonstrates that the available data on maternal RSV vaccine effectiveness and safety are encouraging. Data on uptake suggest that full benefits may not be adequately realised and underscore

the importance of addressing gaps in the evidence base and implementing strategies to increase vaccine coverage.

Contributors

TS conceptualised the study with input from DT and EB. BL, CB, DT, LL, and SF contributed to data collection. EB led data analysis with input from DT and SF. DT and EB wrote the codes for analysis. TS, EB led the data interpretation with contributions from AH, TW, FN, CG, JA, KM, LP, AK, and WSL. EB wrote the first draft of the manuscript with input from TS. All authors contributed to data interpretation and critically revised the manuscript. All authors read and approved the final version of the manuscript. EB, SF, and TS had full access to and verified the underlying data of the study. All authors had final responsibility for the decision to submit for publication.

Data sharing statement

The data that support the findings of this study are fully available within the manuscript.

Declaration of interests

Research funding from Pfizer Inc. is reported by TS for the KHALO study on the impact of an RSV maternal vaccine in Scotland). DT is funded by the Health Data Research UK Inflammation and Immunity Driver Programme. BL has received early career research grants from Asthma + Lung UK. CB has received PhD funding from Health Data Research UK. AH has received grant funding from Pfizer. TW has received funding from the Wellcome Trust for administrative support for the BronchStop study. LP has received MRC funding (UKRI2538; GLAMIRIS RSV birth cohort) and research funding from Pfizer for the BORLAND study on RSV maternal vaccine effectiveness in infants in Scotland.

AK is a member of the Joint Committee on Vaccination and Immunisation RSV subcommittee. WSL reports that their institution received unrestricted investigator-initiated research funding from Pfizer for an unrelated multicentre pneumonia study (ended December 31, 2023) and research funding from the National Institute for Health (NIH) and Care Research for unrelated studies in which WSL is chief investigator or co-applicant. WSL has received funding from NIHR Respiratory Translational Collaboration (R-TRC). WSL chairs JCVI and the Acute Respiratory Infection National Research Strategy Group; both roles are unpaid.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.lanepe.2026.101847.

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