OPEN ACCESS

Original research

Real-world effectiveness and safety of nirsevimab, RSV maternal vaccine and RSV vaccines for older adults: a living systematic review and meta-analysis

Bohee Lee ,[1] Daira Trusinska,[2] Sohail Ferdous,[2] Ruonan Pei,[2] Harley H Y Kwok,[3] Jürgen Schwarze,[4] Thomas Christie Williams,[4] Cheryl Gibbons,[5] Jennifer K Quint ,[3] Aziz Sheikh,[2,6] Simon B Drysdale ,[7,8] Ting Shi [2]

► Additional supplemental material is published online only. To view, please visit the journal online (https://doi.org/10.1136/thorax-2025-223376).

[1]National Heart and Lung Institute, Imperial College London, London, UK
[2]Usher Institute, The University of Edinburgh, Edinburgh, UK
[3]School of Public Health, Imperial College London, London, UK
[4]Child Life and Health, Centre for Inflammation Research, Institute for Regeneration and Repair, The University of Edinburgh, Edinburgh, UK
[5]Vaccination and Immunisation Division, Clinical and Protecting Health Directorate, Public Health Scotland, Edinburgh, UK
[6]Nuffield Department of Primary Care Health Sciences, University of Oxford, Oxford, UK
[7]Oxford Vaccine Group, Department of Paediatrics, University of Oxford, Oxford, UK
[8]NIHR Oxford Biomedical Research Centre, Oxford, UK

Correspondence to
Ting Shi; ting.shi@ed.ac.uk

BL and DT are joint first authors.

Received 28 March 2025
Accepted 26 July 2025

To cite: Lee B, Trusinska D, Ferdous S, *et al*. *Thorax* Epub ahead of print: [*please include* Day Month Year]. doi:10.1136/thorax-2025-223376

ABSTRACT

Background The long-acting monoclonal antibody nirsevimab and respiratory syncytial virus (RSV) vaccines became available for prevention of severe RSV-associated disease in 2023. While clinical trials showed good efficacy and safety, their restrictive inclusion criteria, small sample sizes and short follow-up limit generalisability. We aimed to summarise real-world evidence on the effectiveness and safety of nirsevimab, RSV maternal vaccine and RSV vaccines for older adults.

Methods A living systematic review and meta-analysis, with 5 monthly updated searches in three databases was performed. Eligible studies were published from 1 December 2022 to 10 March 2025. Meta-analyses for the effectiveness of nirsevimab and RSV vaccines were carried out using random-effects model. Safety data were summarised narratively.

Results A total of 50 publications, covering approximately 7.6 million people, were included. Nirsevimab showed 80.7% effectiveness (95% CI: 75.7% to 85.7%; seven studies) against RSV-related emergency department visits, 80.7% (95% CI: 76.1% to 85.2%; 17 studies) against hospital admissions and 75.6% (95% CI: 63.3% to 87.9%; eight studies) against intensive care unit admissions. The effectiveness of RSV vaccines for older adults against RSV-related hospital admissions was 79.6% (95% CI: 73.8% to 85.3; three studies). No effectiveness data were available for RSV maternal vaccine. No severe adverse events were reported for nirsevimab, while RSV vaccines in older adults had fewer than 10 Guillain-Barré syndrome cases per million doses. No severe adverse events were reported for RSV maternal vaccine, although evidence was limited.

Conclusions Our review demonstrated high effectiveness of nirsevimab in reducing RSV-related healthcare utilisation in infants and a favourable safety profile. More evidence is needed for evaluating RSV vaccines in pregnant people and older adults.

PROSPERO registration number CRD42025643585.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ In clinical trials, nirsevimab, the respiratory syncytial virus (RSV) maternal vaccine (ABRYSVO, Pfizer), and the RSV vaccine for adults aged 60 years or older showed great efficacy in reducing RSV-related lower respiratory tract infections, with no substantial safety concerns.

⇒ However, restrictive inclusion criteria, small sample sizes and short follow-up in clinical trials limit the generalisability of efficacy and safety findings to the general population.

WHAT THIS STUDY ADDS

⇒ This is the first living systematic review to evaluate effectiveness and safety of RSV immunisation programmes in the real world.

⇒ Our study confirmed the high effectiveness of nirsevimab and RSV vaccines for older adults, as well as the favourable safety of these immunisation products in real-world conditions. No effectiveness data were available for RSV maternal vaccine.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ In addition to building public confidence in RSV immunisation approaches, our findings highlight areas for further research, such as the waning of immunisation effectiveness over time and population subgroups that need to be studied in more detail as new evidence emerges.

INTRODUCTION

Respiratory syncytial virus (RSV) is a common seasonal cause of significant morbidity and mortality associated with acute lower respiratory tract illness (LRTI) in infants and older adults.[1 2] The burden on healthcare systems is substantial, particularly among infants in their first year of life and adults aged 60 years and above.[2 3] Each year, RSV is responsible for approximately 33 million episodes of LRTI in children under 5 years old, leading to about 3.6 million hospitalisations and 118 200 deaths globally.[3] Notably, over 95% of RSV-related LRTI cases and more than 97% of RSV-related deaths occur in low- and middle-income countries (LMICs), underscoring the substantial global health burden of RSV, especially in resource-limited settings.[1] For older adults, the burden of RSV is also significant, though not as extensively studied as in young children.[2] Recent estimates indicate that, annually in the USA, RSV leads to approximately 60 000–160 000

hospitalisations and 6000–10 000 deaths among adults aged 65 years and older.[4]

In response, passive immunisation with nirsevimab for infants and the maternal vaccine (bivalent RSV prefusion F (RSVpreF) protein-based vaccine, (ABRYSVO, Pfizer)) for pregnant people between 24 and 36 completed weeks of gestation (varied by country) was approved in Europe in October 2022, the UK in November 2022 and the USA in July 2023. Several clinical trials have been conducted, demonstrating favourable safety and efficacy for these products.[5–8] For the maternal vaccine, a clinical trial of the RSVpreF3 (AREXVY, GSK) was halted due to an observed increase in premature births.[9] Only the ABRYSVO (Pfizer) vaccine has been licensed for use during pregnancy, but concerns about the risk of premature births remain. In addition, for older adults, three RSV vaccines—AREXVY (GSK), ABRYSVO (Pfizer) and mRESVIA (Moderna)—were also approved after demonstrating favourable efficacy and good safety profiles in clinical trials.[10 11] However, clinical trials are often limited in their generalisability to real-world settings due to the exclusion of individuals with risk factors and the relatively small sample sizes as reflected in the wide 95% CIs. Rare or very rare serious adverse events such as hypersensitivity reactions, adverse pregnancy outcomes (eg, pre-eclampsia) or cardiovascular or neurological conditions (eg, atrial fibrillation, Guillain-Barré Syndrome (GBS)) may not have been detected in clinical trials. Furthermore, the efficacy of the performance of nirsevimab and vaccines needs to be established in scenarios reflecting those encountered by public health agencies. Since their approval, routine RSV immunisation campaigns have been implemented in countries across Europe, including the UK, and in North America, providing real-world evidence. A growing evidence base demonstrating effectiveness and safety is vital primarily to provide reassurance and build confidence in the vaccines and immunisation programmes, as well as inform decision-makers and policy. To our knowledge, no systematic review has yet assessed the effectiveness and safety of nirsevimab and RSV vaccines using real-world data. To inform immunisation policy, address gaps in evidence from clinical trials and help decision-making, we aimed to conduct a comprehensive review of the effectiveness and safety of RSV prophylaxis in reducing RSV-related healthcare utilisation among infants and older adults in real-world settings.

METHODS

Search strategy and selection criteria

This systematic review follows the PRISMA-P2020 (Preferred Reporting Items for Systematic Review and Meta-analysis Protocols) guidelines.[12] To capture the most up-to-date evidence, we conducted a living systematic review and meta-analysis. The searches were updated monthly over 5 months, from 5 November 2024 to 10 March 2025, following a pre-specified protocol. A protocol for this study was registered on PROSPERO (CRD42025643585).

We searched Ovid Embase, Ovid MEDLINE and Ovid Global Health for literature published between 1 December 2022 and 10 March 2025. Additionally, we hand-searched reference lists of the included studies to identify other relevant publications, including grey literature. Search terms included "respiratory syncytial virus", "RSV", "nirsevimab", "vaccine", "immunisation", "effectiveness" and "safety". The full search strategy is provided in online supplemental table S1.

Eligible studies reported either effectiveness or safety data for nirsevimab or RSV vaccines in real-world settings. Therefore, eligible study designs were observational studies including prospective or retrospective cohort studies, population-based studies using routinely collected healthcare data, registry-based studies or postmarketing surveillance studies. Studies were excluded if they were animal studies, modelling studies, cost-effectiveness analyses or clinical trials. No language or geographical restrictions were applied.

All retrieved studies were uploaded to Covidence, where duplicates were automatically removed.[13] Title and abstract screening, followed by full-text screening, was conducted independently by two of five reviewers (DT, BL, SF, HHYK and RP). Any disagreements were resolved by consensus or by a third reviewer.

Two reviewers independently extracted data using a prespecified data extraction form. Extracted information included study setting, study design, population characteristics and outcomes related to effectiveness and safety. Data extraction was performed using Microsoft Excel, and conflicts were resolved by consensus or by a third reviewer.

Risk of bias was assessed using the Joanna Briggs Institute (JBI) Critical Appraisal Tools, with checklists selected based on study design.[14] Each checklist consisted of 8–11 items covering key domains of bias related to study design, conduct and analysis. As there is no standard JBI interpretation, studies were classified as high risk if they met fewer than 50% of the checklist criteria, moderate risk if they met 51–75% and low risk if they exceeded 75%. Two reviewers independently assessed the risk of bias, with discrepancies resolved through discussion or by a third reviewer.

Data analysis

We defined the effectiveness of nirsevimab and RSV vaccines as the relative reduction in the odds or risk of medical attendance due to RSV infection or LRTI, including bronchiolitis, following prophylaxis. Effectiveness (%) and corresponding 95% CIs using the effect estimates (OR, risk ratio (RR), HR and incidence rate ratio (IRR)) as reported by the studies: effectiveness (%) = 100 × (1−adjusted effect ratio). Several sensitivity analyses were conducted: (1) stratified by different effect estimates (eg, OR, RR, HR or IRR); (2) by pooling unadjusted estimates into overall analysis. Some studies reported statistical estimates without explicitly providing the relative reduction in outcomes; in such cases, we calculated effectiveness based on the reported estimates. For multiple reports from the same study, only the most recent data were included in the meta-analysis.

A separate analysis was conducted for interrupted time series studies, as their comparisons were based on the odds or risk of outcomes at different time points. Different epidemic seasons were analysed in relation to the total number of patients with RSV-related LRTI who used healthcare services. The effectiveness was expressed as a reduction (%) in RSV-related healthcare visits.

We performed a subgroup meta-analysis for each outcome (primary care visits, emergency department (ED) visits, hospital admissions and intensive care unit (ICU) admissions), as well as by country, risk of bias and length of follow-up (≤5 months versus >5 months, as 5 months was the mean follow-up). The I^2 statistic was used to measure the proportion of total variability attributable to between-study heterogeneity, and the τ^2 statistic was used to estimate the absolute between-study variance. Random-effects model was used to pool all estimates, with inverse-variance weighting incorporating an estimate of between-study variance. The impact of publication bias was assessed using Egger's test and funnel plots for meta-analyses containing at least 10 studies.[15]

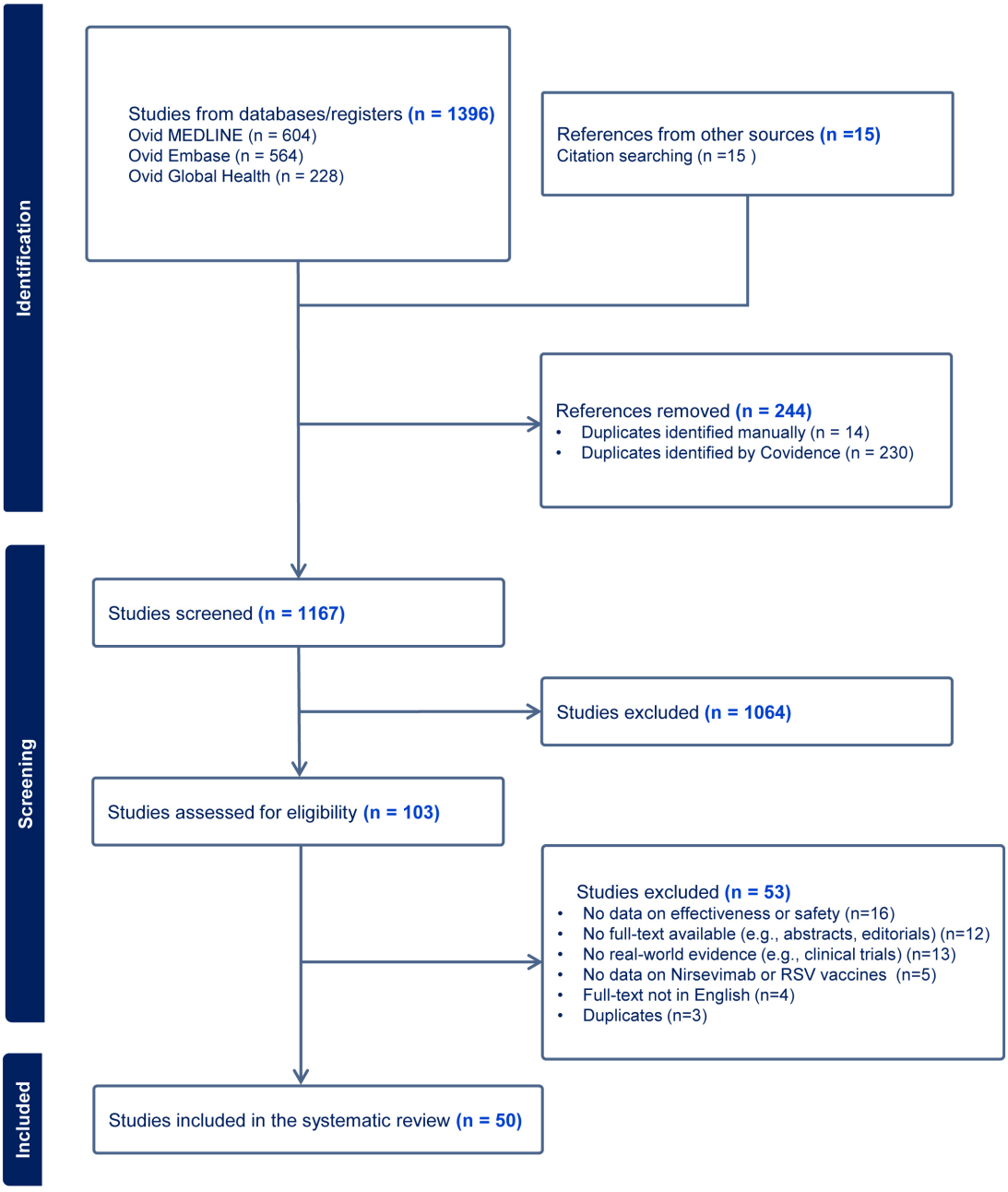

Figure 1 PRISMA flow diagram of study selection. PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses; RSV, respiratory syncytial virus.

For safety outcomes, we conducted a narrative analysis, as most data were reported narratively. Meta-analyses were performed using the 'meta' package in R (V.4.2.3).

Role of funding source

The funder was not involved in the design of this study, data collection, data analysis, interpretation, writing of the manuscript or decision to submit the study for publication.

RESULTS

A total of 1396 publications were retrieved. Following full-text screening, 50 studies were included in this review:[16–65] 39 on nirsevimab (31 reporting exclusively on effectiveness, 6 reporting effectiveness and safety, 2 reporting exclusively on safety), 2 on the maternal RSV vaccine safety and 9 on RSV vaccines for older adults (5 reporting effectiveness and 4 reporting on safety) (figure 1). Studies with various and mixed designs were included: 19 cohort studies (36%), 13 test-negative case-control studies (25%), 14 interrupted time series studies (26%), 3 case-control studies (6%), 2 cross-sectional studies (4%), 1 case series (2%) and 1 quasi-experimental study (2%). Most studies were conducted in Europe (n=34, 68%), predominantly in Spain (n=21, 42%), and France (n=11, 22%). In North America, all included studies were conducted in the USA (n=13, 26%). Online supplemental table S2 provides an overview of the study characteristics.

Most studies were at low risk of bias (n=27, 54%), while 18 studies were classified as having a medium risk of bias (36%) and 5 studies (10%) as having a high risk of bias. Detailed results of the risk of bias assessment are presented in online supplemental table S3.

Effectiveness and safety of nirsevimab for infants

Of the 37 studies reporting the effectiveness of nirsevimab, 31 were included in the meta-analysis (the other 6 studies used interrupted time series design) (figure 2). Three studies were from the same cohort, so we used the latest report.[19 42 44] For preventing RSV-related ED visits, the pooled effectiveness from seven studies was 80.7% (95% CI: 75.7% to 85.7%, I^2=20.1%, τ^2<0.01). The pooled effectiveness against RSV-related hospital admissions, derived from 17 studies, was 80.7% (95% CI: 76.1% to 85.2%, I^2=82.8%, τ^2=56.11). For prevention of RSV-related ICU admissions, the pooled effectiveness from eight studies was 75.6% (95% CI: 63.3% to 87.9%, I^2=74.8%, τ^2=224.92). For preventing RSV-associated primary care visits, two studies were available but could not be included in the meta-analysis due to highly heterogeneous study designs.[21 41] In primary care settings, Lopez-Lacort *et al* study showed that the effectiveness of nirsevimab was 75.8% (95% CI: 40.4% to 92.7%) in infants under 10 months old.[41] Additionally, Barbas Del Buey *et al* differentiated effectiveness by follow-up period (1–5 months) and age (0.5–5 months). Effectiveness ranged from 48.3% to 69.0% in the first month across all age groups, but declined with increasing age, from 69.0% (95% CI: 63.5% to 73.7%) at 0.5 months old to 48.3% (95% CI: 40.9% to 54.9%) at 5 months old.[21]

In sensitivity analyses stratified by different effect estimates of either ORs, RRs, HRs or IRRs, the pooled effectiveness of nirsevimab in preventing RSV-related hospital admissions remained consistent, ranging between 77.4% and 82.3%. The pooled effectiveness for reducing RSV-related ED visits was between 74.7% and 80.0%, and the pooled effectiveness against RSV-related ICU admissions was between 78.4% and 84.6% (online supplemental figure S1). Sensitivity analyses restricted to unadjusted estimates (online supplemental figure S2) or studies with low risk of bias did not significantly differ from the overall estimates (online supplemental figure S3). As funnel plots and Egger's test (p=0.25) were performed only for the meta-analysis of nirsevimab effectiveness on RSV-related hospital admissions (n=17), they indicated a low risk of publication bias (online supplemental figure S4).

We further analysed the studies based on the length of follow-up (online supplemental figure S5). The mean follow-up duration was 5 months, ranging from 15 weeks to 9 months. 18 studies with a follow-up period of 5 months or less and 5 studies with a follow-up period longer than 5 months after immunisation were analysed separately. The meta-estimates were not significantly different. Three studies reported the effectiveness of nirsevimab in preventing RSV-related hospital admissions by child's sex, indicating similar effectiveness: males (78.0%; 95% CI: 64.1% to 91.9%, I^2=88.6%, τ^2=127.98) and females (73.4%; 95% CI: 60.5% to 86.3%, I^2=80.2%, τ^2=82.91) (online supplemental figure S6).[31 33 49] We obtained crude estimates using data provided in one study for preventing RSV-related primary care visits, showing greater effectiveness in males (86%; 95% CI: 40.0% to 97.0%, n=102) compared with females (68%; 95% CI: −42.0% to 93.0%, n=58), although CIs overlapped.[41] The presence of comorbidities in children and preterm births did not significantly affect the overall results (figure 3).

The pooled effectiveness of nirsevimab for preventing all-cause LRTI-related hospital visits, including non-RSV-related LRTI, is summarised in figure 4. The pooled effectiveness for preventing LRTI-related ED visits from four studies was 52.4% (95% CI: 46.1% to 58.6%, I^2=12.5%, τ^2=4.86),[24 26 52 53] while the pooled effectiveness against LRTI-related hospital admissions from five studies was 54.0% (95% CI: 45.6% to 62.4%, I^2=0.0%, τ^2=0.00).[24 42 43 52 56] Two studies reported effectiveness for the prevention of LRTI-related ICU admissions, with a pooled estimate of 68.1% (95% CI: 44.1% to 92.2%, I^2=53.2%, τ^2=178.27).[43 52]

14 interrupted time series studies assessed impact of nirsevimab on RSV-related healthcare utilisation in the 2023/2024 season, compared with previous seasons (online supplemental table S4).[17 18 22 25 27–29 35 39 45 47 51 53 55] 11 studies reported a reduction in RSV-related primary care visits, hospital admissions, ED visits or ICU admissions while one study found that the incidence rates of RSV-related hospitalisations were similar (due to low uptake of nirsevimab). One study reported a decrease in the number of all-cause bronchiolitis cases compared with the previous season (2022/2023).[39] Three studies reported a shift in the median age of infants with RSV-related healthcare utilisation to older ages (indicating fewer healthcare interventions required for younger children and therefore increasing the median age).[22 25 45] The increase in median age ranged from 3 to 6 months for ED visits or hospital admissions.

Eight studies reported mild transient symptoms or no severe adverse events for nirsevimab[19 23 27 28 31 32 42 44] (online supplemental table S5). In a study from Australia, 47 (11.5%) of 410 parents reported one or more adverse events during the 3 days post-nirsevimab administration.[23] The most frequently reported symptoms were fatigue (7.1%), local reaction (2.3%), fever (3.4%) and gastrointestinal issues, which included vomiting/diarrhoea (3.9%). In a study conducted in Italy with 369 children, fever was the most frequent symptom (6.4%), followed by local reaction (4.0%), while 89.2% had no severe adverse events.[27] Adverse events from these two studies are summarised in figure 5. The remaining six studies stated no severe adverse events.

Effectiveness and safety of maternal RSV vaccine

As of 10 March 2025, no studies reporting the effectiveness of maternal RSV vaccination were identified. However, two studies from the USA reported on the safety of the RSV maternal vaccine.[32 54] Homo *et al* did not find adverse outcomes after vaccination.[32] Additionally, Son *et al*[54] found that RSV maternal vaccine was not associated with adverse pregnancy outcomes, including preterm birth (adjusted OR (aOR): 0.87, 95% CI: 0.62 to 1.20), pregnancy-related hypertension (aOR: 1.10, 95% CI: 0.90 to 1.35), small-for-gestational age birth weight (aOR: 1.16, 95% CI: 0.89 to 1.50) and neonatal outcomes including ICU admissions, jaundice, hypoglycaemia or sepsis (all p>0.05). However, only in the time-dependent model, an increased risk of pregnancy-related hypertension was observed (HR: 1.43, 95% CI: 1.16 to 1.77).

Effectiveness and safety of RSV vaccine for older adults

Five studies reported RSV-related healthcare utilisation in older adults after receiving the RSV vaccines (figure 6).[57 59 63–65] Four studies were included in the meta-analysis. The pooled effectiveness was 77.9% (two studies, 95% CI: 73.4% to 82.4%, I^2=0.0%, τ^2=0.00) for preventing RSV-related ED visits,[57 63] and 79.6% (three studies, 95% CI 73.8% to 85.3%, I^2=0.0%, τ^2=0.00) for the prevention of RSV-related hospital admissions.[57 63 64] One study from the UK found a 62.1% (95% CI: 35.0% to 79.8%) reduction in RSV-related hospital admissions during the 2024/2025 RSV season (after introduction of the vaccine) compared with the 2023/2024 RSV season.[59] In a US study, vaccine effectiveness against RSV-related critical illness including ICU admissions and/or in-hospital deaths was 81%

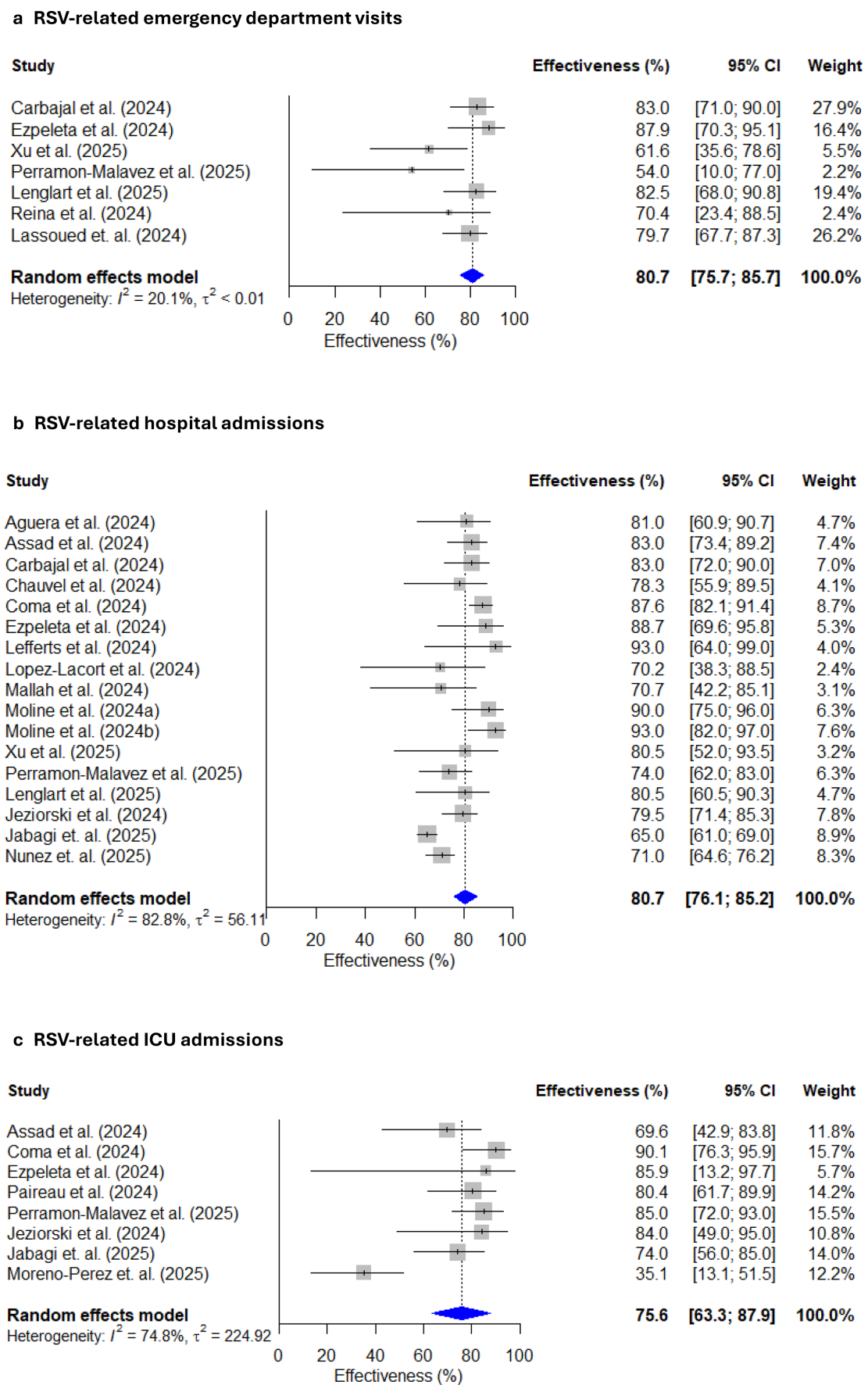

Figure 2 Effectiveness of nirsevimab in infants against respiratory syncytial virus (RSV)-related healthcare utilisation, including emergency department visits, hospital admissions and intensive care unit (ICU) admissions. Note: emergency department visits included data from emergency department, ambulatory care and/or outpatient clinics.

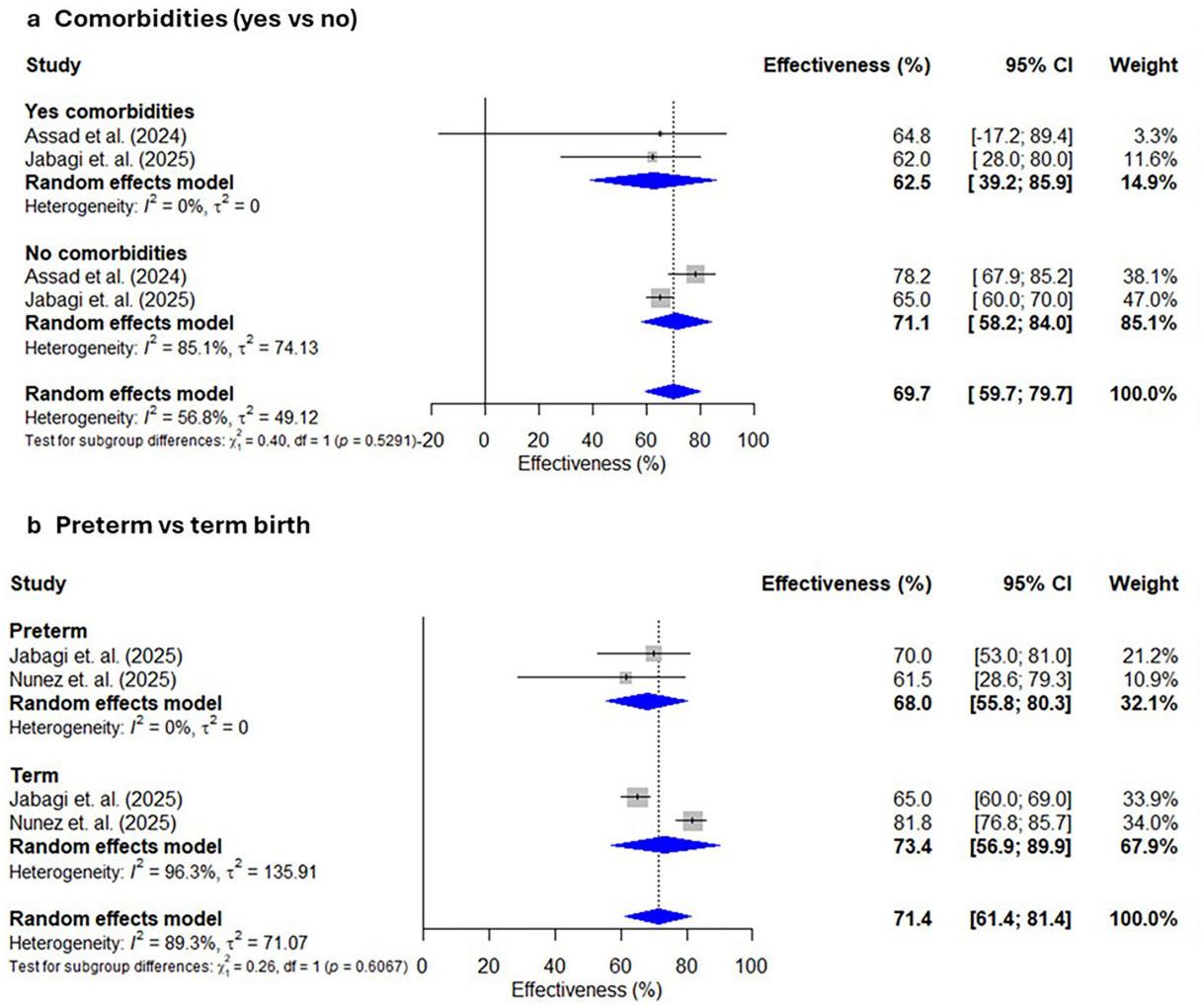

Figure 3 Effectiveness of nirsevimab in infants against respiratory syncytial virus (RSV)-related hospital admission by presence of comorbidities, including preterm births. Note: eligible age criteria varied across the included studies. Detailed eligibility criteria for age are available in online supplemental table S2. Comorbidities included chronic lung disease of prematurity, congenital heart disease or any other previously known comorbidities. Preterm birth was defined as birth at a gestational age of 36 weeks or less.

(95% CI 52% to 92%).[63] In the same study, effectiveness against RSV-related hospital admissions was similar between different vaccine types with overlapping confidence intervals: AREXVY (83%, 95% CI: 73% to 89%) and ABRYSVO (73%, 95% CI: 52% to 85%); and between different age groups with overlapping CIs: 60–74 years (81%, 95% CI: 66% to 90%) and 75 years and above (79%, 95% CI: 68% to 86%).[63]

Four studies reported data on the safety of RSV vaccines in older adults.[58 60–62] Injection site symptoms and systemic symptoms (eg, fatigue/tiredness or muscle pain) constituted 30.0–33.5% and 26.0–29.8% of all reported adverse events, respectively.[60 62] One study reported no association between the RSV vaccine (AREXVY or ABRYSVO) and risk of new-onset atrial fibrillation (RR: 1.06, 95% CI: 0.90 to 1.25) or recurrent atrial fibrillation (RR: 0.94, 95% CI: 0.91 to 0.97) compared with influenza vaccines.[58] In a US study using a self-controlled case series approach, 95 incidents of GBS within 42 days after vaccination were observed among 3.2 million vaccine recipients.[61] They observed the incidence of GBS following both AREXVY (attributable risk: 6.5 GBS cases per one million doses; IRR 2.46, 95% CI: 1.19 to 5.08, 24 cases in risk period, 11 cases in control period) and ABRYSVO (attributable risk: 9 GBS cases per one million doses; IRR 2.02, 95% CI: 0.93 to 4.40, 18 cases in risk period, <11 cases in control period) vaccines within 42 days after vaccination compared with the period between 42 and 90 days postvaccination.[61] Another US study using surveillance data sets found 4.4 and 1.8 GBS cases per one million doses of ABRYSVO and AREXVY vaccine administered, respectively.[60]

DISCUSSION

In this living systematic review, the effectiveness of nirsevimab in reducing medically attended RSV-related disease in real-world settings ranged from 75.6% to 80.7% and the safety profile was favourable. These findings were corroborated by interrupted time series studies comparing data on medically attended RSV-associated disease before and after the implementation of nirsevimab. Interestingly, nirsevimab was associated with over 50% reduction in all-cause LRTI-related hospital visits. In older adults, RSV vaccines showed effectiveness estimates between 77.9% and 79.6% for preventing RSV-related ED visits and RSV-related hospital admissions, respectively. GBS was an adverse event reported in fewer than 10 cases per one million vaccine doses. Despite our monthly updates in searches, no data reporting on the effectiveness of the RSV maternal vaccine in real-world settings was identified and only two studies reported

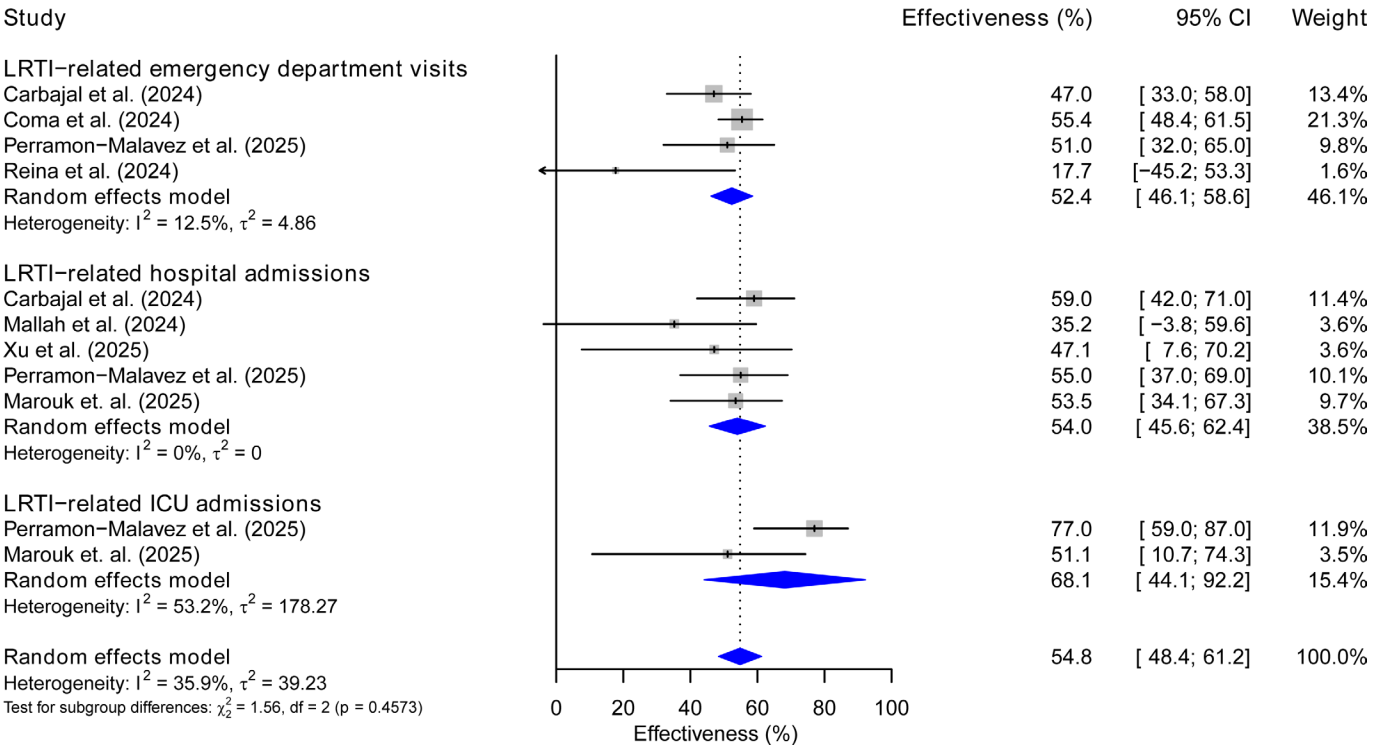

Figure 4 Effectiveness of nirsevimab in infants against all-cause lower respiratory tract illness (LRTI)-related healthcare utilisation, including emergency department visits, hospital admissions and intensive care unit (ICU) admissions.

safety outcomes. Although none of the two studies reported increased incidence of preterm births after the RSV maternal vaccination, current scarcity of data highlights the need for continuous monitoring.

In clinical trials, the efficacy of nirsevimab against RSV-related hospitalisation during the first RSV season ranged from 61% to 90% compared with standard care,[5–8] which was similar to our pooled effectiveness estimates generated from population-based studies. However, it is important to note that the target population for immunisation with nirsevimab varied between the included studies. It was most commonly delivered at under 6 or under 8 months of age, depending on country-specific recommendations owing to factors including product supply, healthcare systems and immunisation service delivery models.

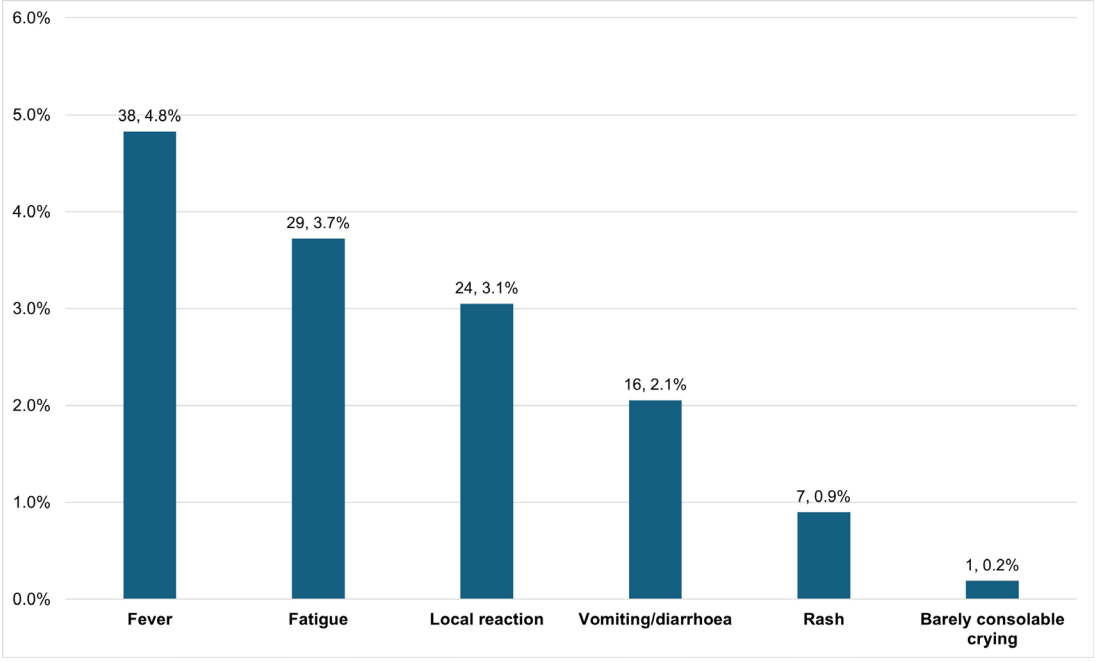

Figure 5 Adverse events of nirsevimab in infants reported in the included studies (n=2 studies*, 779 participants). Note: *among eight studies reporting adverse events of nirsevimab, six reported no adverse events and two reported adverse events.[23 27] None of the reported cases required additional medical visits, and no major events were recorded. In one study, 1.2% (5/410) of children sought medical advice.[23]

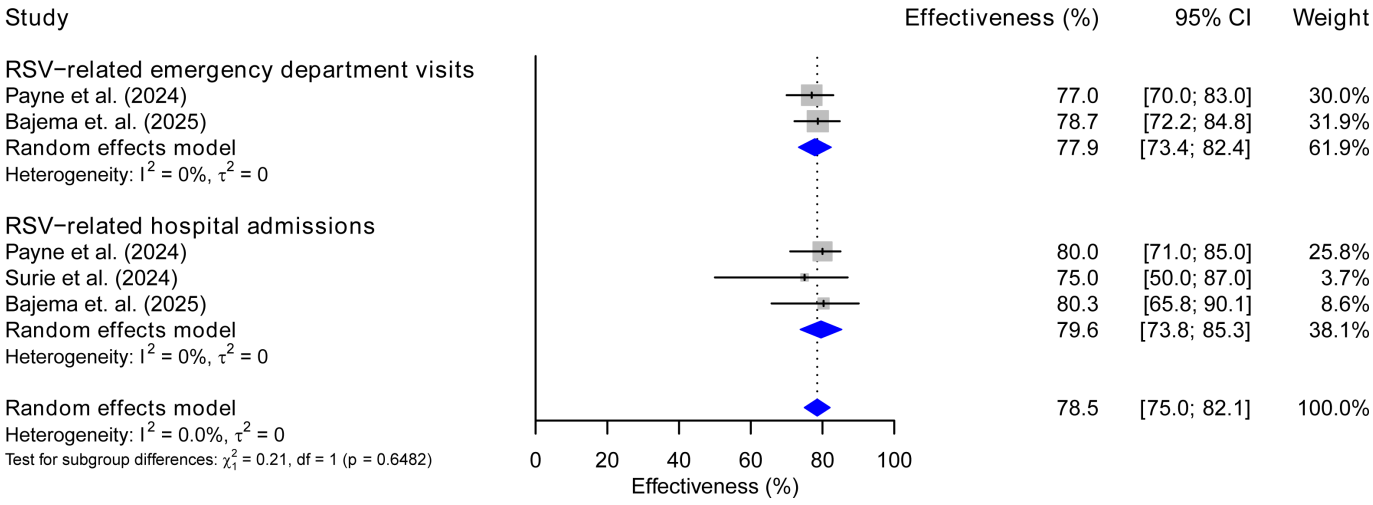

Figure 6 Effectiveness of RSV vaccine for older adults against respiratory syncytial virus (RSV)-related healthcare utilisation, including emergency department visits and hospital admissions. Note: eligible age criteria varied across the included studies. Detailed eligibility criteria for age are available in online supplemental table S2.

For example, in France, soon after the start of the immunisation programme in September 2023, the recommendation shifted from all infants under 8 months of age to newborns in maternity wards only due to unexpectedly high demand and supply shortages.[66 67] By contrast, Spain expanded the use of nirsevimab to premature infants up to 12 months old, achieving high uptake rates exceeding 90%.[68] The effectiveness of nirsevimab did not vary by follow-up length. Although some studies noted the waning of effectiveness over time, there is no consensus on the time frame for this decline. In a study by Xu *et al*, the effectiveness decreased by 24.5% from 2 weeks to 14 weeks postimmunisation.[56] Barbas del Buey *et al* observed a 2–50% decrease over a 5-month follow-up,[21] whereas Jabagi *et al* found no such decline over follow-up of 2.5 months.[33] This decline can be expected, given the pharmacokinetics of nirsevimab[69] and the natural decrease in monoclonal antibody concentration over time, highlighting the importance of timing in nirsevimab immunisation.

The use of nirsevimab for children beyond 1 year old remains debated. The European Medicines Agency and the Australian Therapeutic Goods Administration have approved its use in infants up to 24 months of age who have risk factors for severe RSV disease.[70 71] The US Center for Disease Control and Prevention does not currently recommend nirsevimab for infants aged 20 months or older.[72] Evidence of the effectiveness during children's second RSV season is limited. One study in the USA demonstrated effectiveness of 88.0% (95% CI: 48.0% to 97.0%) in preventing medically attended RSV-related acute respiratory infections during the second RSV season.[37] In our review, we found an increased median age at the time of medically attended RSV infection after the implementation of nirsevimab, which may indicate the need to offer immunisation to older infants as well. More real-world evidence is required to assess how immunisation with nirsevimab impacts RSV-associated disease during children's first and second RSV seasons.

In current practice, a nirsevimab dose of 50 mg is administered to children weighing less than 5000 g and a dose of 100 mg is given to children weighing 5000 g or more. The appropriate dosage for infants with a very low body weight (eg, under 1000 g) has not been ascertained, and limited data are available for this population. In a US study, the effectiveness estimates for the 100 mg and 50 mg doses were comparable, with overlapping CIs.[30] In addition, the effectiveness for preterm infants appears to be similar to that of infants born at term.[16] On the other hand, an increased dose of 200 mg is administered to children 8–19 months old with risk factors in their second RSV season.[72 73] A brief report with 230 children observed a favourable safety profile for the second dose of 200 mg nirsevimab.[72–74] Future research exploring the dose-effectiveness relationship would be beneficial to provide guidance for optimal use of this product depending on children's clinical characteristics.

A clinical trial of the RSVpreF vaccine (ABRYSVO, Pfizer) in pregnant people showed protective effects against medically attended severe LRTI in infants, with an efficacy of 81.8% within 90 days and 69.4% within 180 days after immunisation, compared with the placebo group.[75] While effectiveness has not yet been confirmed in real-world settings due to a lack of data, safety has been supported by the two included US studies.[32 54] These studies found no significant increase in the risk of adverse pregnancy or neonatal outcomes, such as preterm births, small-for-gestational-age birth weight, stillbirth, ICU admissions, respiratory distress, hypoglycaemia, jaundice or hyperbilirubinaemia, or sepsis.[32 54] However, it is important to note that the US vaccination programme only included pregnant people between 32 and 36 weeks of gestation, limiting the opportunity to generate data on preterm birth risk before 32 weeks. In one study, an increased risk of hypertensive disorders of pregnancy was observed only in the time-dependent model, which appeared to be linked to insurance type and hospital site.[54] Therefore, it remains unclear whether hypertensive disorders are a genuine safety concern related to the RSV vaccination. As real-world evidence in different populations and settings remains scarce, further monitoring is needed to assess any potential risks.

Limited evidence was available on the effectiveness and safety of the RSV vaccines for older adults. Our pooled effectiveness meta-estimates were 77.9% for preventing RSV-associated ED visits and 79.6% for preventing RSV-related hospital admissions, which are slightly different from estimates from clinical trials (efficacy of over 80% in preventing RSV-related LRTI).[10] Additionally, the development of GBS after vaccination was reported in fewer than 10 cases per one million vaccine doses. It is recognised as a serious but rare adverse event in the product information documents for ABRYSVO (which may affect up to 1 in 1000 people).[76] GBS is also known to be an adverse event following the influenza vaccine, though the incidence is much

lower, with fewer than one case per million doses.[77] As RSV vaccines become available for more people worldwide, further surveillance of the incidence of GBS and other rare safety signals in older adults will be crucial for accurate risk estimation.

The limited evidence could partially be attributed to poor linkage between healthcare databases or inadequate reporting systems for the older adult population in some countries. In the USA, reporting of influenza and RSV vaccination coverage for residents of nursing homes is optional, meaning that only facilities that voluntarily submit data are included. This can introduce potential selection bias, as facilities that report such data may be more likely to offer these vaccines.[78] Barriers such as high cost and vaccine hesitancy may also limit RSV vaccine uptake, contributing to the limited data. For instance, the high cost of RSV vaccines compared with the influenza or COVID-19 vaccines may create financial barriers for individuals and nursing homes. In the USA, the cost of RSV vaccines is significantly higher than that of the influenza vaccine (US$75.54) or COVID vaccines (US$141.80). The AREXVY and ABRYSVO vaccines are priced at US$294.00 and US$295.00 per dose, respectively.[79] Beyond cost, vaccine hesitancy related to safety and efficacy concerns, along with general non-vaccination behaviours, may also contribute to low RSV vaccine uptake in this population.[80] As this is a new vaccine, it may take time for the vaccine programme to mature and for public trust to increase, highlighting the need for educational campaigns for vaccine recipients and providers and implementation of other strategies to address barriers to vaccine uptake.

Our comprehensive living systematic review and meta-analysis provides up-to-date evidence on the effectiveness and safety of RSV immunisation products against RSV-related severe disease. However, it is important to acknowledge several methodological limitations. First, most of the included studies in our review were peer-reviewed studies, and data from governmental and public health agencies were not sought out. New evidence on the effectiveness and safety of RSV prophylactics is rapidly emerging and may be reported by public health agencies before studies are published; therefore, it is possible that some data were missed in our review. However, we included studies published up to 10 March 2025, and will update the living systematic review as new studies are published. Second, the included studies were conducted in eight high-income countries which may limit generalisability to LMICs. For instance, most of the effectiveness data for nirsevimab were contributed by studies from Spain, which has high immunisation uptake rates (online supplemental figure S7). However, an early press release from a study on RSV maternal vaccine in Argentina suggests similar effectiveness to that observed in clinical trials: effectiveness of 72.7% (95% CI: 60.0% to 81.4%) and 68.0% (95% CI: 56.2% to 76.6%) in preventing RSV-associated LRTI hospitalisations in infants aged 0–3 months old and 0–6 months old, respectively.[81] Estimates of immunisation effectiveness may vary across countries due to differences in uptake rates, immunisation strategies, monitoring systems or potential delays in data entry into healthcare databases. These factors are likely to contribute to the high heterogeneity observed between studies in the meta-analysis (high I^2 or τ^2 statistics). Third, models for effect estimates underlying the calculated vaccine effectiveness varied across studies. To address this limitation, we conducted sensitivity analyses by each effect estimate and unadjusted estimates but found no significant differences. Fourth, some duplication of study populations is possible; however, where possible, we only included the most recent data covering the same study population in the meta-analysis. For example, three studies reported data from the NIRSE-GAL population-based study, a longitudinal study initiated in collaboration with the Galician Directorate of Public Health of the Xunta de Galicia, but to avoid duplication, data only from Mallah *et al* were included.[42] Finally, the RSVpreF maternal vaccine may be offered year-round in some countries, but on an extended seasonal or seasonal basis in others; additionally, in some countries, it may only be offered from a certain gestational age.[82] As a result, data on effectiveness and safety may be limited initially for comparison as data accumulation may take an entire year or several RSV seasons. Especially, lack of studies reporting severe adverse events does not necessarily imply the absence of substantial safety signals—ongoing monitoring of the safety of RSV prophylactics is crucial. As more evidence becomes available from a wider range of geographical settings and population subgroups, more granular effectiveness and safety estimates, as well as insights into waning effects over time, will be possible.

CONCLUSION

This is the first comprehensive overview of the effectiveness and safety of nirsevimab, the RSV maternal vaccine and RSV vaccines for older adults in a real-world setting. Nirsevimab demonstrated a favourable safety profile and high effectiveness in preventing medically attended RSV-related disease, including ED visits, hospitalisations and ICU admissions in infants. For the RSV maternal vaccine and RSV vaccines for older adults, data on effectiveness and safety in real-world conditions are currently scarce; therefore, evaluation of the evidence in these populations is essential. Ongoing monitoring of effectiveness and safety is paramount for informing guidelines, public health agencies and clinical decision-making, as well as reassuring the public and building confidence in immunisation programmes which have the potential to reduce the burden of RSV-associated disease in the most vulnerable groups.

Acknowledgements AS and DT acknowledged the support of Health Data Research UK.

Contributors TS conceptualised the study with input from DT, TCW and AS. BL, DT, SF, RP and HHYK contributed to data collection. BL led data analysis with input from DT. BL wrote the codes for analysis. TS, SBD, AS, TCW led data interpretation. BL wrote the first draft of the manuscript with input from TS and DT. BL, DT, SF, RP, HHYK, JS, TCW, CG, JKQ, AS, SBD and TS contributed to data interpretation and critically revised the manuscript. BL, DT, SF, RP, HHYK, JS, TCW, CG, JKQ, AS, SBD and TS read and approved the final draft of the manuscript. BL, DT and TS had full access to and verified all the study data. BL, DT, SF, RP, HHYK, JS, TCW, CG, JKQ, AS, SBD and TS had final responsibility for the decision to submit for publication. TS is the guarantor of the study.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests BL has received research funding from Asthma + Lung UK. TS received funding from the National Institute of Health and Care Research (NIHR). DT, SF, RP, HHYK, JS, TCW, CG, JKQ, AS, SBD declare no competing interests.

Patient consent for publication Not applicable.

Ethics approval Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request.

ORCID iDs
Bohee Lee http://orcid.org/0000-0002-9671-386X
Jennifer K Quint http://orcid.org/0000-0003-0149-4869
Simon B Drysdale http://orcid.org/0000-0002-6350-6557
Ting Shi http://orcid.org/0000-0002-4101-4535

REFERENCES

1 Li Y, Wang X, Blau DM, *et al*. Global, regional, and national disease burden estimates of acute lower respiratory infections due to respiratory syncytial virus in children younger than 5 years in 2019: a systematic analysis. *Lancet* 2022;399:2047–64.
2 Kenmoe S, Nair H. The disease burden of respiratory syncytial virus in older adults. *Curr Opin Infect Dis* 2024;37:129–36.
3 Mazur NI, Caballero MT, Nunes MC. Severe respiratory syncytial virus infection in children: burden, management, and emerging therapies. *Lancet* 2024;404:1143–56.
4 CDC. Use of respiratory syncytial virus vaccines in older adults: recommendations of the advisory committee on immunization practices — United States, 2023. 2023. Available: https://ndc.services.cdc.gov/case-definitions/respiratory-syncytial-virus-associated-mortality-2019
5 Drysdale SB, Cathie K, Flamein F, *et al*. Nirsevimab for Prevention of Hospitalizations Due to RSV in Infants. *N Engl J Med* 2023;389:2425–35.
6 Hammitt LL, Dagan R, Yuan Y, *et al*. Nirsevimab for Prevention of RSV in Healthy Late-Preterm and Term Infants. *N Engl J Med* 2022;386:837–46.
7 Griffin MP, Yuan Y, Takas T, *et al*. Single-Dose Nirsevimab for Prevention of RSV in Preterm Infants. *N Engl J Med* 2020;383:415–25.
8 Muller WJ, Madhi SA, Seoane Nuñez B, *et al*. Nirsevimab for Prevention of RSV in Term and Late-Preterm Infants. *N Engl J Med* 2023;388:1533–4.
9 Dieussaert I, Hyung Kim J, Luik S, *et al*. RSV Prefusion F Protein-Based Maternal Vaccine - Preterm Birth and Other Outcomes. *N Engl J Med* 2024;390:1009–21.
10 Walsh EE, Pérez Marc G, Zareba AM, *et al*. Efficacy and Safety of a Bivalent RSV Prefusion F Vaccine in Older Adults. *N Engl J Med* 2023;388:1465–77.
11 Wilson E, Goswami J, Baqui AH, *et al*. Efficacy and Safety of an mRNA-Based RSV PreF Vaccine in Older Adults. *N Engl J Med* 2023;389:2233–44.
12 Page MJ, McKenzie JE, Bossuyt PM, *et al*. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ* 2021;372:n71.
13 Covidence. Covidence systematic review software: veritas health innovation. Melbourne, Australia, 2025. Available: https://www.covidence.org
14 Joanna briggs institute. *Critical appraisal tools for use in JBI systematic reviews*. 2020.
15 Egger M, Davey Smith G, Schneider M, *et al*. Bias in meta-analysis detected by a simple, graphical test. *BMJ* 1997;315:629–34.
16 Agüera M, Soler-Garcia A, Alejandre C, *et al*. Nirsevimab immunization's real-world effectiveness in preventing severe bronchiolitis: A test-negative case-control study. *Pediatr Allergy Immunol* 2024;35:e14175.
17 Alejandre C, Penela-Sánchez D, Alsina J, *et al*. Impact of universal immunization program with monoclonal antibody nirsevimab on reducing the burden of serious bronchiolitis that need pediatric intensive care. *Eur J Pediatr* 2024;183:3897–904.
18 Andina Martínez D, Claret Teruel G, Gijón Mediavilla M, *et al*. Nirsevimab and Acute Bronchiolitis Episodes in Pediatric Emergency Departments. *Pediatrics* 2024;154:e2024066584.
19 Ares-Gómez S, Mallah N, Santiago-Pérez M-I, *et al*. Effectiveness and impact of universal prophylaxis with nirsevimab in infants against hospitalisation for respiratory syncytial virus in Galicia, Spain: initial results of a population-based longitudinal study. *Lancet Infect Dis* 2024;24:817–28.
20 Assad Z, Romain A-S, Aupiais C, *et al*. Nirsevimab and Hospitalization for RSV Bronchiolitis. *N Engl J Med* 2024;391:144–54.
21 Barbas Del Buey JF, Íñigo Martínez J, Gutiérrez Rodríguez MÁ, *et al*. The effectiveness of nirsevimab in reducing the burden of disease due to respiratory syncytial virus (RSV) infection over time in the Madrid region (Spain): a prospective population-based cohort study. *Front Public Health* 2024;12:1441786.
22 Cantais A, Annino N, Thuiller C, *et al*. First RSV epidemic with nirsevimab. Older children than previous epidemics, even when hospitalized. *J Med Virol* 2024;96:e29483.
23 Carcione D, Spencer P, Pettigrew G, *et al*. ACTIVE POST-MARKETING SAFETY SURVEILLANCE OF NIRSEVIMAB ADMINISTERED TO CHILDREN IN WESTERN AUSTRALIA, APRIL-JULY 2024. *Pediatr Infect Dis J* 2025.
24 Carbajal R, Boelle P-Y, Pham A, *et al*. Real-world effectiveness of nirsevimab immunisation against bronchiolitis in infants: a case–control study in Paris, France. *Lancet Child Adolesc Health* 2024;8:730–9.
25 Chauvel C, Horvat C, Javouhey E, *et al*. Changes in Respiratory Syncytial Virus-Associated Hospitalisations Epidemiology After Nirsevimab Introduction in Lyon, France. *Influenza Other Respir Viruses* 2024;18:e70054.
26 Coma E, Martinez-Marcos M, Hermosilla E, *et al*. Effectiveness of nirsevimab immunoprophylaxis against respiratory syncytial virus-related outcomes in hospital and primary care settings: a retrospective cohort study in infants in Catalonia (Spain). *Arch Dis Child* 2024;109:736–41.
27 Consolati A, Farinelli M, Serravalle P, *et al*. Safety and Efficacy of Nirsevimab in a Universal Prevention Program of Respiratory Syncytial Virus Bronchiolitis in Newborns and Infants in the First Year of Life in the Valle d'Aosta Region, Italy, in the 2023-2024 Epidemic Season. *Vaccines (Basel)* 2024;12:549.
28 Ernst C, Bejko D, Gaasch L, *et al*. Impact of nirsevimab prophylaxis on paediatric respiratory syncytial virus (RSV)-related hospitalisations during the initial 2023/24 season in Luxembourg. *Euro Surveill* 2024;29:2400033.
29 Espeleta-Fox A, García-Salido A, Vallespín-Casas A, *et al*. Impact of nirsevimab on admission to a Spanish pediatric intensive care unit because of RSV bronchiolitis: Unicentric observational study from 2017 to 2024. *Pediatr Pulmonol* 2024;59:3783–6.
30 Estrella-Porter P, Blanco-Calvo C, Lameiras-Azevedo AS, *et al*. Effectiveness of nirsevimab introduction against respiratory syncytial virus in the Valencian Community: A preliminary assessment. *Vaccine (Auckl)* 2024;42:126030.
31 Ezpeleta G, Navascués A, Viguria N, *et al*. Effectiveness of Nirsevimab Immunoprophylaxis Administered at Birth to Prevent Infant Hospitalisation for Respiratory Syncytial Virus Infection: A Population-Based Cohort Study. *Vaccines (Basel)* 2024;12:383.
32 Homo RL, Groberg A, Donahue M, *et al*. High Uptake of Respiratory Syncitial Virus Prevention for Neonates in a Military Treatment Facility. *J Pediatr* 2024;273:114144.
33 Jabagi MJ, Cohen J, Bertrand M, *et al*. Nirsevimab Effectiveness at Preventing RSV-Related Hospitalization in Infants. *NEJM Evid* 2025;4:EVIDoa2400275.
34 Jeziorski E, Ouziel A, Cotillon M, *et al*. Impact of Nirsevimab on Respiratory Syncytial Virus Bronchiolitis in Hospitalized Infants: A Real-World Study. *Pediatr Infect Dis J* 2025;44:e124–6.
35 Jimeno Ruiz S, Peláez A, Labourt A, *et al*. Evaluating the Effectiveness of Nirsevimab in Reducing Pediatric RSV Hospitalizations in Spain. *Vaccines (Basel)* 2024;12:1160.
36 Lassoued Y, Levy C, Werner A, *et al*. Effectiveness of nirsevimab against RSV-bronchiolitis in paediatric ambulatory care: a test-negative case-control study. *Lancet Reg Health Eur* 2024;44:101007.
37 Lefferts B, Bressler S, Keck JW, *et al*. Nirsevimab Effectiveness Against Medically Attended Respiratory Syncytial Virus Illness and Hospitalization Among Alaska Native Children - Yukon-Kuskokwim Delta Region, Alaska, October 2023-June 2024. *MMWR Morb Mortal Wkly Rep* 2024;73:1015–21.
38 Lenglart L, Levy C, Basmaci R, *et al*. Nirsevimab effectiveness on paediatric emergency visits for RSV bronchiolitis: a test-negative design study. *Eur J Pediatr* 2025;184:171.
39 Levy C, Werner A, Rybak A, *et al*. Early Impact of Nirsevimab on Ambulatory All-Cause Bronchiolitis: A Prospective Multicentric Surveillance Study in France. *J Pediatric Infect Dis Soc* 2024;13:371–3.
40 López-Lacort M, Muñoz-Quiles C, Mira-Iglesias A, *et al*. Early estimates of nirsevimab immunoprophylaxis effectiveness against hospital admission for respiratory syncytial virus lower respiratory tract infections in infants. *Euro Surveill* 2023;29:2400046.
41 López-Lacort M, Muñoz-Quiles C, Mira-Iglesias A, *et al*. Nirsevimab Effectiveness Against Severe Respiratory Syncytial Virus Infection in the Primary Care Setting. *Pediatrics* 2025;155:e2024066393.
42 Mallah N, Pardo-Seco J, Pérez-Martínez O, *et al*. Full 2023-24 season results of universal prophylaxis with nirsevimab in Galicia, Spain: the NIRSE-GAL study. *Lancet Infect Dis* 2025;25:e62–3.
43 Marouk A, Verrat B, Pontais I, *et al*. Effectiveness of nirsevimab in reducing hospitalizations in emergency departments due to bronchiolitis among infants under 3 months: a retrospective study. *Eur J Pediatr* 2025;184:229.
44 Martinón-Torres F, Mirás-Carballal S, Durán-Parrondo C. Early lessons from the implementation of universal respiratory syncytial virus prophylaxis in infants with long-acting monoclonal antibodies, Galicia, Spain, September and October 2023. *Euro Surveill* 2023;28:2300606.
45 Molina Gutiérrez MÁ, de Miguel Lavisier B, Ruiz Domínguez JA, *et al*. Impact of nirsevimab immunization on RSV infections attended in the pediatric emergency department: First results in a tertiary hospital in Madrid. *Enfermedades Infecciosas y Microbiologia Clinica (English Ed)* 2024;42:367–72.
46 Moline HL, Tannis A, Toepfer AP, *et al*. Early Estimate of Nirsevimab Effectiveness for Prevention of Respiratory Syncytial Virus-Associated Hospitalization Among Infants Entering Their First Respiratory Syncytial Virus Season - New Vaccine Surveillance Network, October 2023-February 2024. *MMWR Morb Mortal Wkly Rep* 2024;73:209–14.
47 Moline HL, Toepfer AP, Tannis A, *et al*. Respiratory Syncytial Virus Disease Burden and Nirsevimab Effectiveness in Young Children From 2023-2024. *JAMA Pediatr* 2025;179:179–87.
48 Moreno-Pérez D, Korobova A, Croche-Santander F de B, *et al*. Nirsevimab Prophylaxis for Reduction of Respiratory Syncytial Virus Complications in Hospitalised Infants: The Multi-Centre Study During the 2023-2024 Season in Andalusia, Spain (NIRSEGRAND). *Vaccines (Basel)* 2025;13:175.
49 Núñez O, Olmedo C, Moreno-Perez D, *et al*. Effectiveness of catch-up and at-birth nirsevimab immunisation against RSV hospital admission in the first year of life: a population-based case-control study, Spain, 2023/24 season. *Euro Surveill* 2025;30:2400596.

50 Paireau J, Durand C, Raimbault S, *et al*. Nirsevimab Effectiveness Against Cases of Respiratory Syncytial Virus Bronchiolitis Hospitalised in Paediatric Intensive Care Units in France, September 2023–January 2024. *Influenza Resp Viruses* 2024;18:e13311.
51 Perramon-Malavez A, de Rioja VL, Coma E, *et al*. Introduction of nirsevimab in Catalonia, Spain: description of the incidence of bronchiolitis and respiratory syncytial virus in the 2023/2024 season. *Eur J Pediatr* 2024;183:5181–9.
52 Perramon-Malavez A, Hermosilla E, Coma E, *et al*. Effectiveness of Nirsevimab Immunoprophylaxis Against Respiratory Syncytial Virus-related Outcomes in Hospital Care Settings: A Seasonal Cohort Study of Infants in Catalonia, Spain. *Pediatr Infect Dis J* 2025;44:394–8.
53 Reina J, Iturbe A, Viana-Ramírez J, *et al*. Comparative analysis of acute respiratory infections of viral etiology in children under 6 months with and without nirsevimab in the Balearic Islands (2022–2023 and 2023–2024). *Enfermedades Infecciosas y Microbiologia Clinica (English Ed)* 2025;43:193–6.
54 Son M, Riley LE, Staniczenko AP, *et al*. Nonadjuvanted Bivalent Respiratory Syncytial Virus Vaccination and Perinatal Outcomes. *JAMA Netw Open* 2024;7:e2419268.
55 Vazquez-Lopez P, Rivas-Garcia A, Luaces-Cubells C, *et al*. Changes in Care in Spanish Pediatric Emergency Departments After the First Immunization With Nirsevimab. *Pediatr Emerg Care* 2025;41:365–71.
56 Xu H, Aparicio C, Wats A, *et al*. Estimated Effectiveness of Nirsevimab Against Respiratory Syncytial Virus. *JAMA Netw Open* 2025;8:e250380.
57 Bajema KL, Yan L, Li Y, *et al*. Respiratory syncytial virus vaccine effectiveness among US veteransRespiratory syncytial virus vaccine effectiveness among US veterans, September, 2023 to March, 2024: a target trial emulation study. *Lancet Infect Dis* 2025;25:625–33.
58 Birabaharan M, Johns ST, Kaelber DC, *et al*. Atrial Fibrillation After Respiratory Syncytial Virus Vaccination Among Older Adults. *Clin Infect Dis* 2024.
59 Hameed SS, Robertson C, Morrison K, *et al*. Early evidence of RSV vaccination impact on hospitalisation rates of older people in Scotland. *Lancet Infect Dis* 2025;25:256–8.
60 Hause AM, Moro PL, Baggs J, *et al*. Early Safety Findings Among Persons Aged ≥60 Years Who Received a Respiratory Syncytial Virus Vaccine - United States, May 3, 2023-April 14, 2024. *MMWR Morb Mortal Wkly Rep* 2024;73:489–94.
61 Lloyd PC, Shah PB, Zhang HT, *et al*. Evaluation of guillain-barré syndrome following respiratory syncytial virus vaccination among medicare beneficiaries 65 years and older. *medRxiv* [Preprint] 2025.
62 Nguyen T, Dawes L, Huang YA, *et al*. Short term safety profile of respiratory syncytial virus vaccine in adults aged ≥ 60 years in Australia. *Lancet Reg Health West Pac* 2025;56:101506.
63 Payne AB, Watts JA, Mitchell PK, *et al*. Respiratory syncytial virus (RSV) vaccine effectiveness against RSV-associated hospitalisations and emergency department encounters among adults aged 60 years and older in the USA, October, 2023, to March, 2024: a test-negative design analysis. *Lancet* 2024;404:1547–59.
64 Surie D, Self WH, Zhu Y, *et al*. RSV Vaccine Effectiveness Against Hospitalization Among US Adults 60 Years and Older. *JAMA* 2024;332:1105–7.
65 Tartof SY, Aliabadi N, Goodwin G, *et al*. Estimated Vaccine Effectiveness for Respiratory Syncytial Virus-Related Lower Respiratory Tract Disease. *JAMA Netw Open* 2024;7:e2450832.
66 lepharmacien. Beyfortus a évité 5 800 hospitalisations pour bronchiolite. 2024. Available: https://www.lepharmacien.fr/blog-pharmacien/article/beyfortus-a-evite-5800-hospitalisations-pour-bronchiolite
67 Morris T, Acevedo K, Alvarez Aldeán J, *et al*. Lessons from implementing a long-acting monoclonal antibody (nirsevimab) for RSV in France, Spain and the US. *Discov Health Systems* 2025;4:21.
68 CAV-AEP. Ministerio de Sanidad: recomendaciones de uso de nirsevimab en la temporada 2024-25. 2024. Available: https://vacunasaep-org.translate.goog/profesionales/noticias/ministerio-de-sanidad-recomendaciones-de-uso-de-nirsevimab-en-la-temporada-2024-25?_x_tr_sl=es&_x_tr_tl=en&_x_tr_hl=en&_x_tr_pto=sc
69 Jorgensen SCJ. Nirsevimab: review of pharmacology, antiviral activity and emerging clinical experience for respiratory syncytial virus infection in infants. *J Antimicrob Chemother* 2023;78:1143–9.
70 Australian Government Department of Health and Aged Care. Older infants and young children ≥8 to 24 months of age who are at risk of severe RSV disease are recommended to receive RSV-specific monoclonal antibody before their 2nd RSV season. 2025. Available: https://immunisationhandbook.health.gov.au/recommendations/older-infants-and-young-children-8-to-24-months-of-age-who-are-at-risk-of-severe-rsv-disease-are-recommended-to-receive-rsv-specific-monoclonal-antibody-before-their-2nd-rsv-season
71 European Medicines Agency. Beyfortus. 2025. Available: https://www.ema.europa.eu/en/medicines/human/EPAR/beyfortus
72 CDC. RSV immunization guidance for infants and young children. 2024. Available: https://www.cdc.gov/rsv/hcp/vaccine-clinical-guidance/infants-young-children.html
73 European Medicines Agency. Beyfortus : EPAR - Product information. 2025. Available: https://www.ema.europa.eu/en/documents/product-information/beyfortus-epar-product-information_en.pdf
74 Domachowske JB, Chang Y, Atanasova V, *et al*. Safety of Re-dosing Nirsevimab Prior to RSV Season 2 in Children With Heart or Lung Disease. *J Pediatric Infect Dis Soc* 2023;12:477–80.
75 Kampmann B, Madhi SA, Munjal I, *et al*. Bivalent Prefusion F Vaccine in Pregnancy to Prevent RSV Illness in Infants. *N Engl J Med* 2023;388:1451–64.
76 European Medicines Agency. Abrysvo: EPAR - Medicine overview. 2023. Available: https://www.ema.europa.eu/en/medicines/human/EPAR/abrysvo
77 Perez-Vilar S, Hu M, Weintraub E, *et al*. Guillain-Barré Syndrome After High-Dose Influenza Vaccine Administration in the United States, 2018-2019 Season. *J Infect Dis* 2021;223:416–25.
78 Reses HE, Segovia G, Dubendris H, *et al*. Coverage with Influenza, Respiratory Syncytial Virus, and COVID-19 Vaccines Among Nursing Home Residents - National Healthcare Safety Network, United States, November 2024. *MMWR Morb Mortal Wkly Rep* 2024;73:1052–7.
79 CDC. Current CDC vaccine price list. 2025. Available: https://www.cdc.gov/vaccines-for-children/php/awardees/current-cdc-vaccine-price-list.html?CDC_AAref_Val=https://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/index.html
80 Motta M, Callaghan T, Padmanabhan M, *et al*. Quantifying the prevalence and determinants of respiratory syncytial virus (RSV) vaccine hesitancy in US adults aged 60 or older. *Public Health (Fairfax)* 2025;238:3–6.
81 iTRIALS-Equipo Ciencia and UNSAM present first results of the BERNI study [press release]. 2025.
82 Pecenka C, Sparrow E, Feikin DR, *et al*. Respiratory syncytial virus vaccination and immunoprophylaxis: realising the potential for protection of young children. *Lancet* 2024;404:1157–70.