Context

- Respiratory syncytial virus (RSV) is a common respiratory virus that causes mild symptoms in most people; however, it can manifest as serious lower respiratory tract disease (LRTD)/lower respiratory tract infection (LRTI) in infants and older adults with underlying conditions or weakened immune systems.
- RSV is one of the most significant causes of excess morbidity and mortality in older adults,(1) and is associated with 52.7 hospitalizations per 100,000 people over the age of 65 years annually.(2)
- Adults with certain underlying chronic conditions are at increased risk of RSV-associated LRTD/ LRTI, with 9.5% of U.S. adults 18 to 49 years and 24.3% of those 50 to 64 years at risk.(3; 4)
- In Canada, RSV also has a greater impact on infant and child populations.
  - While high-risk infants face a greater risk of severe outcomes, healthy term infants contribute most to the overall healthcare burden.(5)
  - Nationally, about 1% of Canadian infants are hospitalized with RSV in their first year.(6)
  - Children in remote northern communities face a disproportionate burden of RSV hospitalization, with rates ranging from 20 to 50% of all live births in some areas.(6)
- AREXVY™ (RSVPreF3) by GlaxoSmithKline, ABRYSVO™ (RSVpreF) by Pfizer, and mRESVIA™ by Moderna are vaccines that are authorized in Canada to prevent LRTD/LRTI caused by RSV in adults.
- For infant protection, Health Canada has authorized the monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi, ENFLONSI™(clesrovimab) by Merck, and SYNAGIS® (palivizumab), as well as the ABRYSVO™ (RSVpreF) vaccine by Pfizer, which provides passive immunity.
  - The National Advisory Committee on Immunization (NACI) currently recommends nirsevimab and clesrovimab for immunization programs while they await more data on RSVpreF.(6)
- Monitoring vaccine performance through effectiveness studies is crucial for understanding and improving vaccination benefits, and for evaluating how circulating and evolving RSV types affect vaccine performance in both clinical settings and real-world conditions, while also considering various outcomes and populations.
- The Public Health Agency of Canada aims to monitor the post-market effectiveness, and impact of RSV vaccines over time to support vaccine policy, enhance situational awareness, inform routine briefings, and ultimately protect Canadians from severe illness.
- This evidence synthesis has been developed to inform these efforts.
  - It builds on a previous version (RES 127.1, March 2025),(7) which examined the efficacy and effectiveness of RSV vaccines and monoclonal antibodies against lower respiratory tract disease in older adults and infants across a broader set of outcomes and research questions.
  - The current evidence synthesis introduces several refinements to that scope to strengthen the relevance of findings for vaccine policy decision-making; these changes are described in the research questions section below.

Rapid evidence synthesis

Effectiveness of respiratory syncytial virus vaccines and monoclonal antibodies against lower respiratory tract disease in older adults and infants

1 April 2026

[MHF product code: RES 127.2]

Questions

From the previous report to the current report, changes to the primary and secondary research questions were made. The two original primary questions (one on efficacy, one on effectiveness) have been consolidated into a single primary question focused exclusively on effectiveness. The efficacy question has not been updated in this report, but the findings from the first version have been retained for reference.(7) They will be updated in a future iteration.

In addition, the outcomes analyzed in this version have been narrowed. The previous report addressed three tiers of outcomes: LRTD/LRTI, medically attended LRTD/LRTI, and severe LRTD/LRTI. This version now focuses on the following: medically attended LRTD, hospitalization, ICU admission and severe LRTD. Broad LRTD/LRTI without the "medically attended" qualifier has been removed as a standalone outcome.

Lastly, the three secondary research questions have been removed. The nirsevimab hospitalization question (previously secondary question 2) and the waning effectiveness question (previously secondary question 1) have been incorporated directly into the primary question. The high-risk adults 18–59 question (previously secondary question 3) has been dropped.

The updated research question for this current report is as follows:

- What is the effectiveness of RSV vaccines (Abrysvo by Pfizer, Arexvy by GSK, and mRESVIA by Moderna) against medically attended LRTD and severe LRTD in older adults aged ≥60 years and newborns (via vaccinated mothers)? Additionally, what is the effectiveness of nirsevimab (Beyfortus) and clesrovimab (Enflonsi) against hospitalization in children ≤2 year?

Box 1: Approach and supporting materials

We retrieved candidate studies by searching: 1) Medline, 2) Embase via OVID, 3) Preprint Citation Index (e.g. bioRiv, medRxiv); 4) Cochrane CENTRAL; and 5) ClinicalTrials.gov. We also included studies identified by subject-matter experts who reviewed the protocols and final report. Searches were conducted for studies reported in English, French, Spanish, Portuguese, Arabic, and Chinese conducted with humans and published since database inception until 5 January 2026. Our detailed search strategy is included in Appendix 1.

For effectiveness outcomes, any experimental design such as interventional trials or observational designs including cohort, test-negative case-control, before-after studies, interrupted time-series, and case series were considered for inclusion. For all outcomes, evidence syntheses were tracked, and any relevant primary studies from them were pulled out for our analysis. A full list of included studies is provided in Appendices 2 and 3. Studies excluded at the last stages of reviewing are provided in Appendix 4.

Population of interest: Older adults aged ≥60 years, children less than 2 years of age

Intervention and control/comparator: Intervention: three RSV vaccines named AREXVY™ (RSVPreF3), ABRYSVO™ (RSVpreF), and mRESVIA™(mRNA-1345) as well as the monoclonal antibodies BEYFORTUS™ (nirsevimab) and ENFLONSI™ (clesrovimab); Control: Unvaccinated individuals.

Outcomes: 1) medically attended lower respiratory tract disease (LRTD)/ lower respiratory tract infection (LRTI); 2) RSV-related hospitalization; and 3) severe LRTD/LRTI.

Data extraction: Data extraction was conducted by one team member.

Critical appraisal: A PRISMA flow diagram is provided in Appendix 5. The risk of bias (ROB) of individual studies was assessed using validated ROB tools. For randomized controlled trials, we used RoB-2, and for observational studies, we used ROBINS-I. Judgments for the domains within these tools were decided by one reviewer and details are provided in Appendix 6.

Summaries: We summarized the evidence by presenting narrative

High-level summary of key findings

Evidence identified

- We identified 4,495 articles, and after removing 717 duplicates, we screened 3,683 titles and abstracts.
- We reviewed 176 full-text articles and included 83 articles (published between 2020 to 2026), of which 58 were newly identified in this update:
  - 13 studies were randomized clinical trials
  - 70 were non-randomized clinical studies (e.g. test-negative case-control, prospective cohort study, retrospective cohort study), of which 58 were newly identified in this update.
- The risk of bias results at the outcome level are provided in the Excel sheet provided in Appendix 6 on the web-based project page.

Key findings for RSV immunization product effectiveness

- Nirsevimab demonstrated high effectiveness in infants and children <2 years, providing 82% protection against RSV-related hospitalizations (36 studies), 80% protection against ICU admission (17 studies), 82% protection against severe disease requiring oxygen support (6 studies), and 80% protection against medically attended RSV infection across primary care and emergency department settings (16 studies), though effectiveness wanes over time, declining from approximately 76% at 2–4 weeks to 55% by 12–14 weeks for medically attended infection, while protection against severe outcomes remained more durable.
- Maternal RSVpreF vaccination (ABRYSVO™) provided 79% protection against RSV-related hospitalization in infants (7 studies) with low heterogeneity, and individual studies reported 87–90% protection against ICU admission, though limited data on medically attended outcomes and no data on duration of protection were available.
- RSVpreF (ABRYSVO™) and RSVPreF3 (AREXVY™) vaccines in older adults ≥60 years provided 76% protection against both RSV-related hospitalizations (7 studies) and emergency department visits (4 studies), with individual studies reporting 67–92% protection against severe disease; effectiveness waned from approximately 89% at 1 month to 57% at 18 months, with more pronounced decline among immunocompromised individuals.
- No included studies examined the effectiveness of clesrovimab (ENFLONSIA®) or mRESVIA™ against RSV-related outcomes.

Key findings for RSV immunization product efficacy

All four efficacy bullet points below are retained unchanged from RES 127.1 as no new efficacy data has been added to this version.(7)

- Nirsevimab monoclonal antibody (BEYFORTUS™) demonstrates high efficacy (70–86%) in preventing RSV infections and hospitalizations in infants, with consistent results across multiple studies.
- Maternal RSVpreF vaccination (ABRYSVO™) provides significant protection to infants (51–100% efficacy), with strongest effects in the first 90 days of life and against severe disease.
- For adults ≥60 years, GSK's RSVPreF3 (AREXVY™) and Pfizer's RSVpreF (ABRYSVO™) vaccines show strong efficacy (67–94% and 59–86%, respectively) against RSV-related respiratory illness.
- Moderna's mRNA-1345 (mRESVIA™) demonstrates approximately 84% efficacy against RSV-LRTD in older adults, with better protection against RSV-A (92%) than RSV-B (69%).

What we found

We identified 4,495 articles, and after removing 717 duplicates, we screened 3,683 titles and abstracts. We reviewed 176 full-text articles and included 83 articles (published between 2020 to 2026), of which 58 were newly identified in this update. For observational studies with multiple publications based on the same data source, only one publication was included to avoid duplication of data, with selection based on the completeness of the available data. Data from Papi (2023) (8) and Ison

(2024) (9) are from a single trial (AReSVi-006) testing GSK's RSVPreF3 OA vaccine. Similarly, Walsh (2023) (10) and Walsh (2024) (11) report data from the same RENOIR trial testing Pfizer's bivalent RSVpreF vaccine, with the 2024 publication providing extended two-season efficacy results. Additionally, Otsuki (2024) presented a Japan subset analysis of Kampmann's (2023) study (MATISSE).(12) To avoid duplicate data, we only included Ison (2024), Walsh (2024), and Kampmann (2023) in our analysis.

These studies included the following:

- 13 randomized clinical trials
  - the risk of bias in the randomized studies was low in eight; there were some concerns in three of the included studies
  - 70 non-randomized clinical studies (e.g., test-negative case-control, prospective cohort, retrospective cohort study), of which 58 were newly identified in this update.
  - the risk of bias (ROBINS-I) results at the outcome level for the non-randomized studies are provided in the Excel sheet provided in Appendix 6 on the web-based project page.
- The 83 studies spanned multiple geographic regions:
  - Africa (South Africa, Gambia)
  - Asia (Japan, Philippines, South Korea)
  - Australasia (Australia, New Zealand).
  - Europe (Spain, France, Germany, U.K., Netherlands, Finland, Scotland, Belgium, Andorra, Denmark)
  - North America (U.S., Canada)
  - South America (Argentina, Brazil, Chile)

A summary of the characteristics of the individual studies included, such as its population, study design, type of vaccine and efficacy/effectiveness outcomes assessed, is provided in Table 1 (effectiveness studies) and Table 2 (efficacy studies). In general, the studies analyze similar outcomes, namely RSV-related LRTD/LRTI, RSV-related acute respiratory infection/disease (ARI/ARD), RSV-related bronchiolitis outcomes, and RSV-related outcomes without specifically classifying them as LRTD/ LRTI, ARI or bronchiolitis outcomes. We extracted the outcomes explicitly following what authors reported in their original articles. The diagnostic criteria varied slightly between studies; for details of the definition of each outcome, please refer to each study.

1. Effectiveness of RSV immunization products

1.1 Infants and children aged <2 years

1.1.1 Nirsevimab monoclonal antibody (BEYFORTUS™)

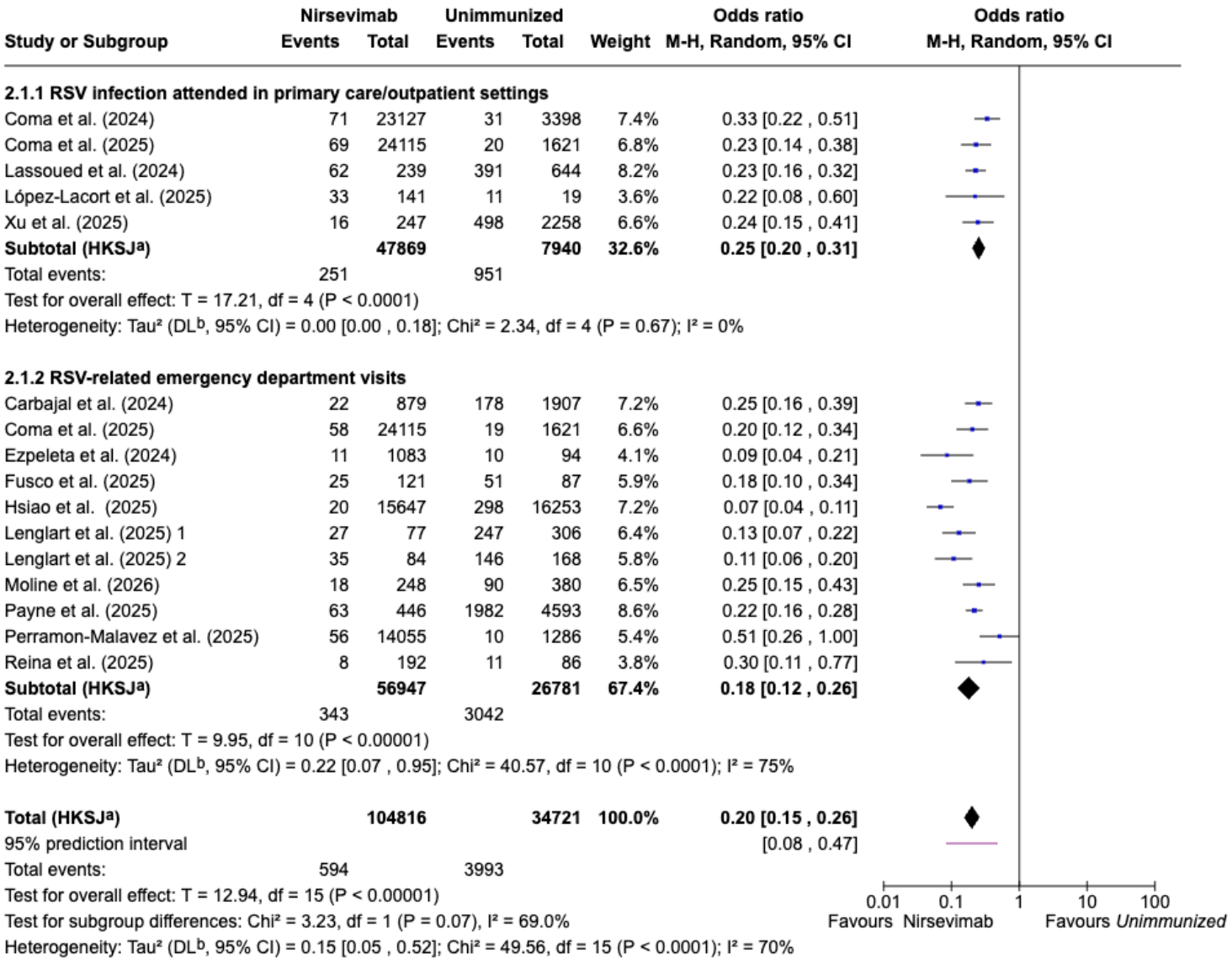
The four old outcome subcategories under nirsevimab (LRTD/LRTI, ARI, bronchiolitis) are narrowed to two: medically attended LRTD, hospitalization, ICU, and severe LRTD. Studies excluded under the updated criteria are removed, and newly identified studies from the January 2026 search have been added.

Medically attended RSV-related LRTD/LRTI outcomes

Sixteen studies were pooled in the meta-analysis evaluating the effectiveness of nirsevimab among infants across primary care/outpatient and emergency department settings (Figure 1). In the subgroup of pooled analyses of five studies conducted in primary-care or outpatient settings, nirsevimab was associated with lower odds of medically attended RSV infection (OR 0.25, 95% CI 0.20–0.31), corresponding to a 75% effectiveness (95% CI 69.0–80.0), with no observed heterogeneity (τ^2=0.00; I^2=0%). In the subgroup of pooled analyses of 11 studies evaluating RSV-related emergency department visits, nirsevimab was associated with lower odds of RSV-related visits (OR 0.18, 95% CI 0.12–0.26), corresponding to an 82% effectiveness (95% CI 74.0–88.0), with substantial heterogeneity (τ^2=0.22; I^2=75%). When data from both clinical settings were combined (n=16; 104,816 immunized and 34,721 unimmunized participants), nirsevimab was associated with a reduction in the odds of medically attended RSV infection (OR 0.20, 95% CI 0.15–0.26), corresponding to an 80% effectiveness (95% CI 74.0–85.0), with substantial heterogeneity (τ^2=0.15; I^2=70%). The test for subgroup differences

suggested a trend toward greater effectiveness for emergency department visits compared with primary-care or outpatient encounters, though this did not reach statistical significance (Chi² = 3.23, df = 1, p = 0.07; I² = 69%).

Figure 1: Effectiveness of nirsevimab against outpatient medically attended RSV infection among infants and children <2 years)



Footnotes

[a]CI calculated by Hartung-Knapp-Sidik-Jonkman method.

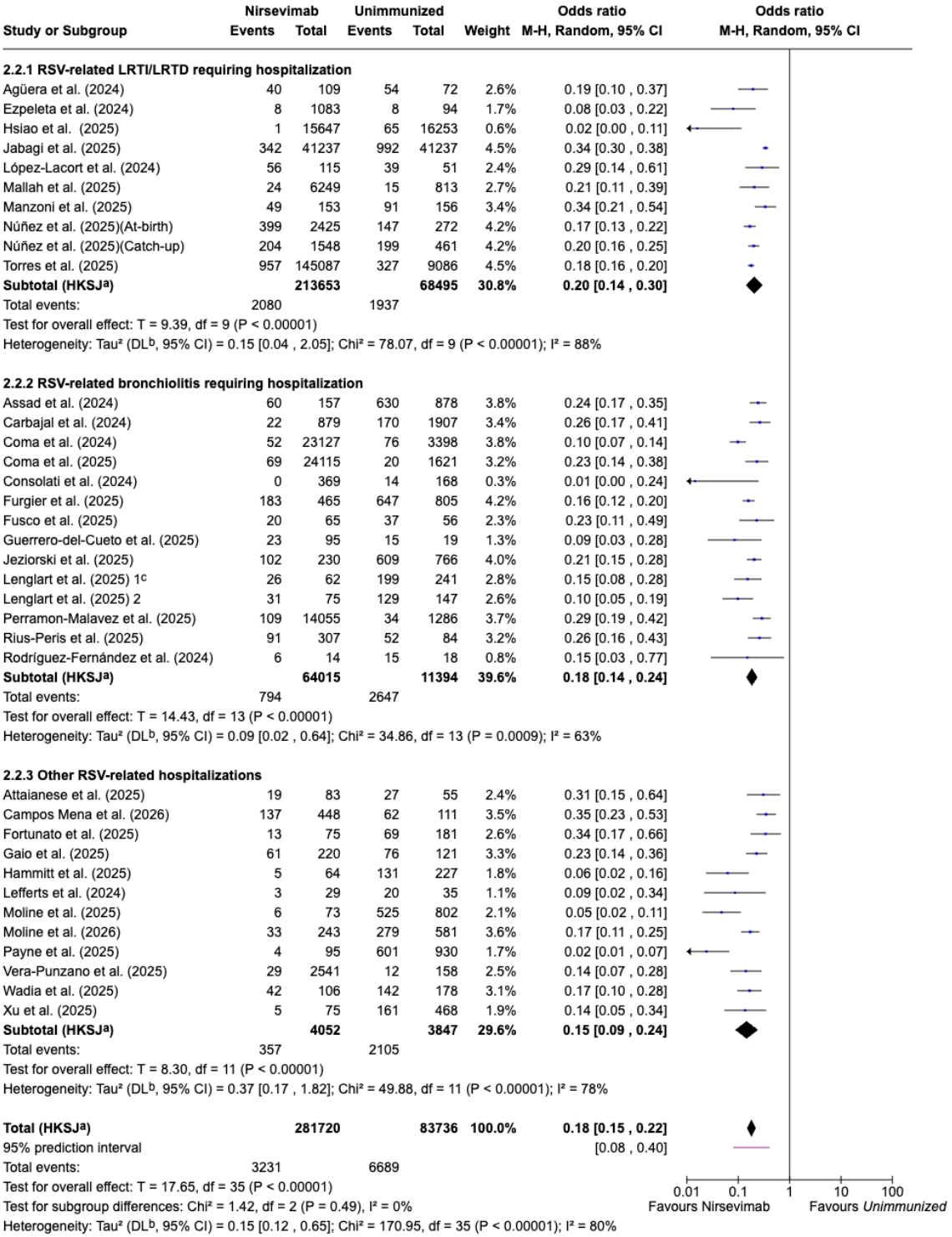
[b]Tau² calculated by DerSimonian and Laird method.

RSV-related hospitalization outcomes

Thirty-six studies were pooled in the meta-analysis evaluating the effectiveness of nirsevimab against RSV-related hospitalization across three clinical subgroups (Figure 2). In the subgroup of pooled analyses of 10 studies evaluating RSV-related LRTI/LRTD requiring hospitalization, nirsevimab was associated with lower odds of hospitalization (OR 0.20, 95% CI 0.14–0.30), corresponding to an 80.0% effectiveness (95% CI 70.0–86.0), with high heterogeneity (τ^2=0.15; I^2=88%). In the subgroup of pooled analyses of 14 studies evaluating RSV-related bronchiolitis requiring hospitalization, nirsevimab was associated with lower odds of hospitalization (OR 0.18, 95% CI 0.14–0.24), corresponding to an 82% effectiveness (95% CI 76–86), with substantial heterogeneity (τ^2=0.09; I^2=63%). In the subgroup of pooled analyses of 12 studies evaluating other RSV-related hospitalizations, nirsevimab was associated with lower odds of hospitalization (OR 0.15, 95% CI 0.09–0.24),

corresponding to an 85% effectiveness (95% CI 76.0–91.0), with high heterogeneity (τ^2=0.37; I^2=78%). When data from all three clinical subgroups were combined (n=36; 281,720 immunized and 83,736 unimmunized participants), nirsevimab was associated with a reduction in the odds of RSV-related hospitalization (OR 0.18, 95% CI 0.15–0.22), corresponding to an 82% effectiveness (95% CI 78.0–85.0), with high heterogeneity (τ^2=0.15; I^2=80%). No statistically significant subgroup differences were observed between the three hospitalization subgroups (Chi^2=1.42, df=2, p=0.49; I^2=0%).

Figure 2: Effectiveness of nirsevimab against RSV-related hospitalization among infants and children <2 years)



Footnotes

[a]CI calculated by Hartung-Knapp-Sidik-Jonkman method.

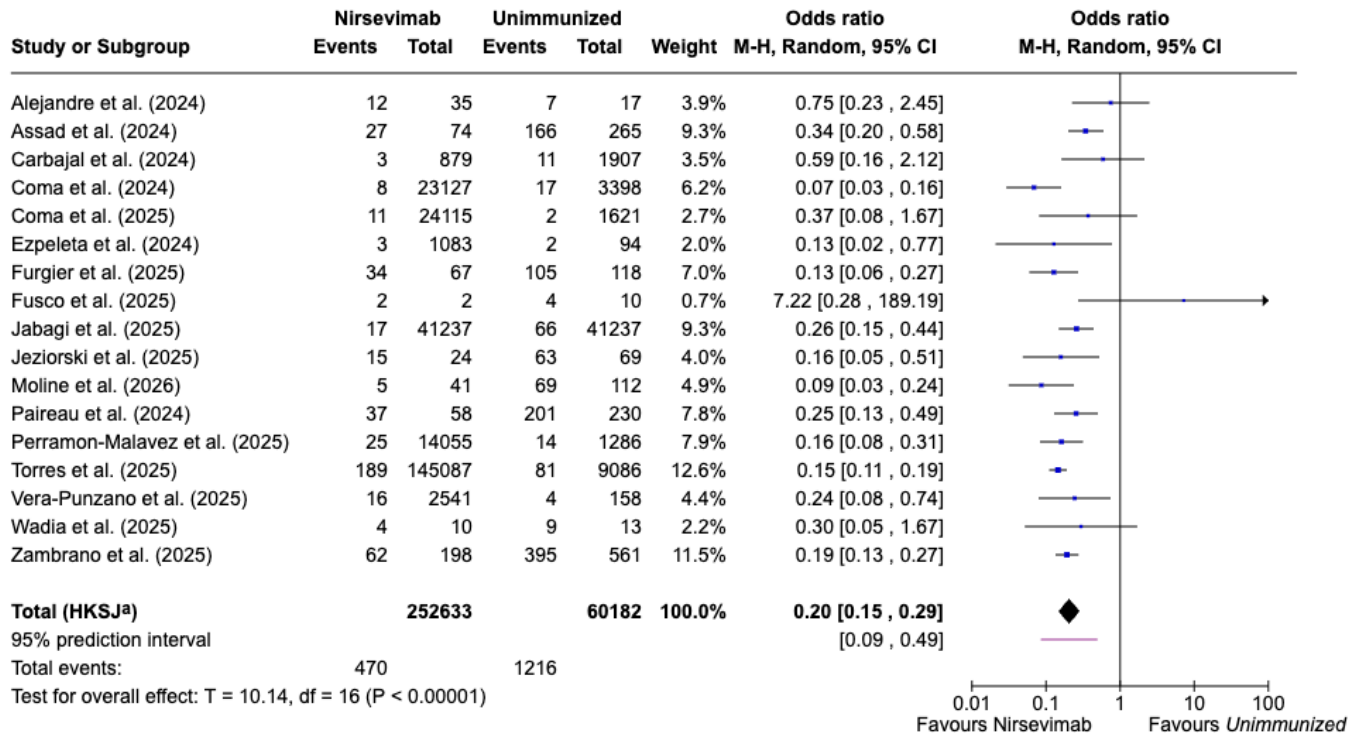
[b]Tau² calculated by DerSimonian and Laird method.

[c]2023-2024 season

RSV-related ICU outcomes

Seventeen studies were pooled in the meta-analysis evaluating the effectiveness of nirsevimab against RSV-related ICU admission (Figure 3). When data from all studies were combined (n=17; 252,633 immunized and 60,182 unimmunized participants), nirsevimab was associated with a reduction in the odds of RSV-related ICU admission (OR 0.20, 95% CI 0.15–0.29), corresponding to an 80% effectiveness (95% CI 71–85), with moderate heterogeneity (τ^2=0.14; I^2=54%).

Figure 3: Effectiveness of nirsevimab against RSV-related ICU among infants and children <2 years)

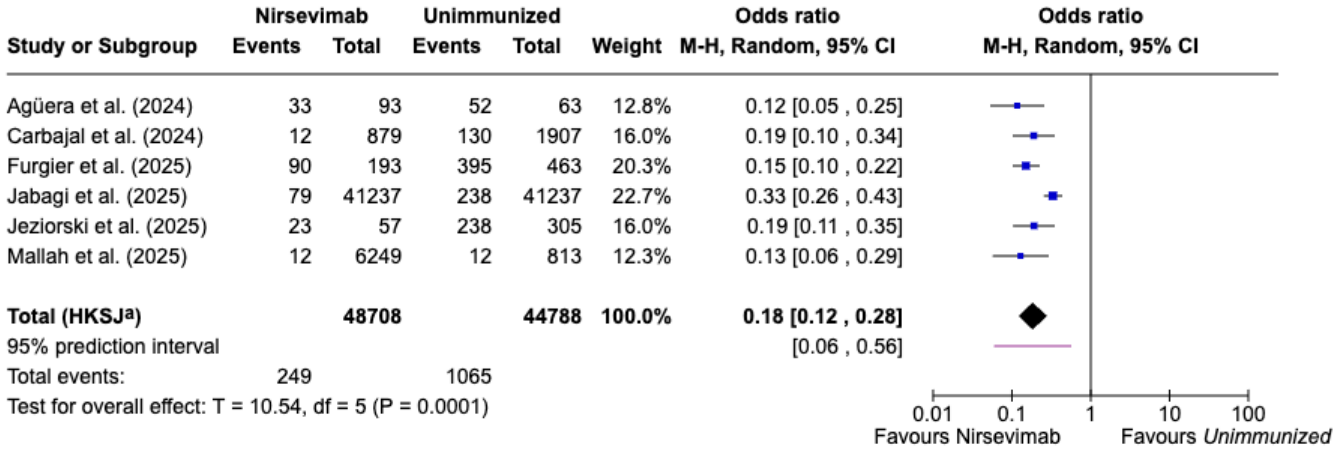


RSV-related severe disease

Six studies were pooled in the meta-analysis evaluating the effectiveness of nirsevimab against RSV-related outcomes requiring oxygen support (Figure 4). When data from all studies were combined (n=6; 48,708 immunized and 44,788 unimmunized participants), nirsevimab was associated with a reduction in the odds of RSV-related oxygen support requirement (OR 0.18, 95% CI 0.12–0.28), corresponding to an 82% effectiveness (95% CI 72–88), with substantial heterogeneity (τ^2=0.16; I^2=73%).

Five studies were pooled in the meta-analysis evaluating the effectiveness of nirsevimab against RSV-related outcomes requiring ventilation support (Figure 5). When data from all studies were combined (n=5; 41,565 immunized and 41,995 unimmunized participants), nirsevimab was associated with a reduction in the odds of RSV-related ventilation support requirement (OR 0.25, 95% CI 0.17–0.37), corresponding to a 75% effectiveness (95% CI 63–83), with moderate heterogeneity (τ^2=0.11; I^2=59%).

Figure 4: Effectiveness of nirsevimab against RSV-related outcomes requiring oxygen support among infants and children <2 years)



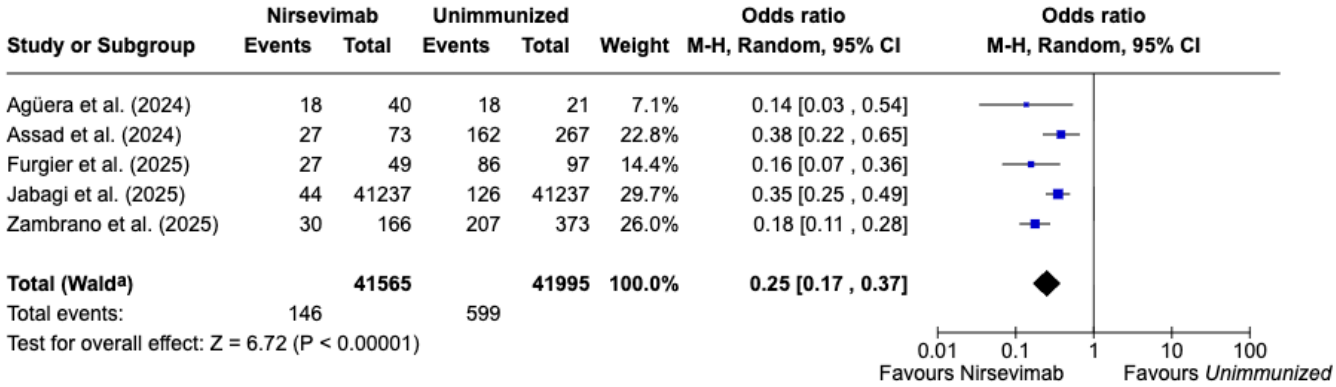
Heterogeneity: Tau² (DL[b], 95% CI) = 0.16 [0.01 , 0.78]; Chi² = 18.40, df = 5 (P = 0.002); I² = 73%

Footnotes

[a]CI calculated by Hartung-Knapp-Sidik-Jonkman method.

[b]Tau² calculated by DerSimonian and Laird method.

Figure 5: Effectiveness of nirsevimab against RSV-related outcomes requiring ventilation support among infants and children <2 years



Heterogeneity: Tau² (DL[b], 95% CI) = 0.11 [0.00 , 1.69]; Chi² = 9.71, df = 4 (P = 0.05); I² = 59%

Footnotes

[a]CI calculated by Wald-type method.

[b]Tau² calculated by DerSimonian and Laird method.

Duration of protection

Because limited studies evaluated the waning effectiveness of nirsevimab in preventing RSV-related outcomes in infants, a meta-analysis was not performed.

Xu et al. (2025) observed a clear pattern of time-dependent waning in nirsevimab effectiveness across all-measured RSV outcomes. During the early post-immunization period (>2–4 weeks), nirsevimab maintained high levels of protection, with effectiveness estimated at 76.1% (95% CI: 60.1–87.3) against medically attended RSV infection, 88.4% (95% CI: 66.6–97.4) for RSV-associated hospitalization, and 93.2% (95% CI: 75.1–99.2) for severe RSV disease requiring high-flow oxygen or ICU care. Over time, protection declined across outcomes, with effectiveness against medically attended RSV infection falling to 54.8% (95% CI: 16.3–74.7) by more than 12–14 weeks post-immunization; corresponding more than 10–12 week

estimates for RSV-associated hospitalization and severe RSV disease were 73.6% (95% CI: 23.7–92.1) and 77.5 (95% CI: 20.8–94.5), respectively.(13)

Barbas Del Buey et al. (2024) observed a modest decline over time in nirsevimab effectiveness, though protection against severe RSV-related outcomes remained high throughout the follow-up period in the Madrid region. During the early post-immunization period (30 days), nirsevimab maintained very high levels of protection, with effectiveness estimated at 93.6% (95% CI: 89.7–96.1) against RSV-associated hospitalization and 94.4% (95% CI: 87.3–97.5) against ICU admission. Protection remained robust over time, with effectiveness against hospitalization remaining as high as 87.6% (95% CI: 67.7–95.3) at 150 days, while ICU-specific effectiveness at 90 days was 92.1% (95% CI: 64.0–98.3). Although protection against primary-care consultations and emergency visits was lower than for severe outcomes, with an overall estimated effectiveness of 59.3% for primary care, the intervention consistently reduced the RSV disease burden across all levels of care.(14)

However, Coma et al. (2025) evaluated the long-term impact of nirsevimab among infants in their second year of life, finding that the clinical benefits of immunization during infancy extended across two consecutive RSV seasons. Over the two-season study period, nirsevimab conferred a profound reduction in the cumulative incidence of severe outcomes: RSV-associated hospitalizations were 9.57 per 1,000 in the immunized group versus 35.56 per 1,000 in the non-immunized group (RR 0.27; 95% CI: 0.20–0.40; VE 73% (95% CI: 60.0–80.0)). PICU admissions were similarly reduced (RR 0.21; 95% CI: 0.11–0.48; VE 79% (95% CI: 52.0–89.0). Notably, while the direct preventive effect against milder, primary care–recorded RSV infections was no longer statistically significant by the second year (RR 0.81; 95% CI: 0.57–1.29), the initial protection during the first year of life significantly lowered the total two-year healthcare burden.(15)

1.1.2 Clesrovimab monoclonal antibody (ENFLONSIA ®)

None of the included studies examined the effectiveness of clesrovimab against RSV-related outcomes in adults aged 60 years and older.

1.1.3 Maternal RSVpreF vaccine (ABRYSVO™)

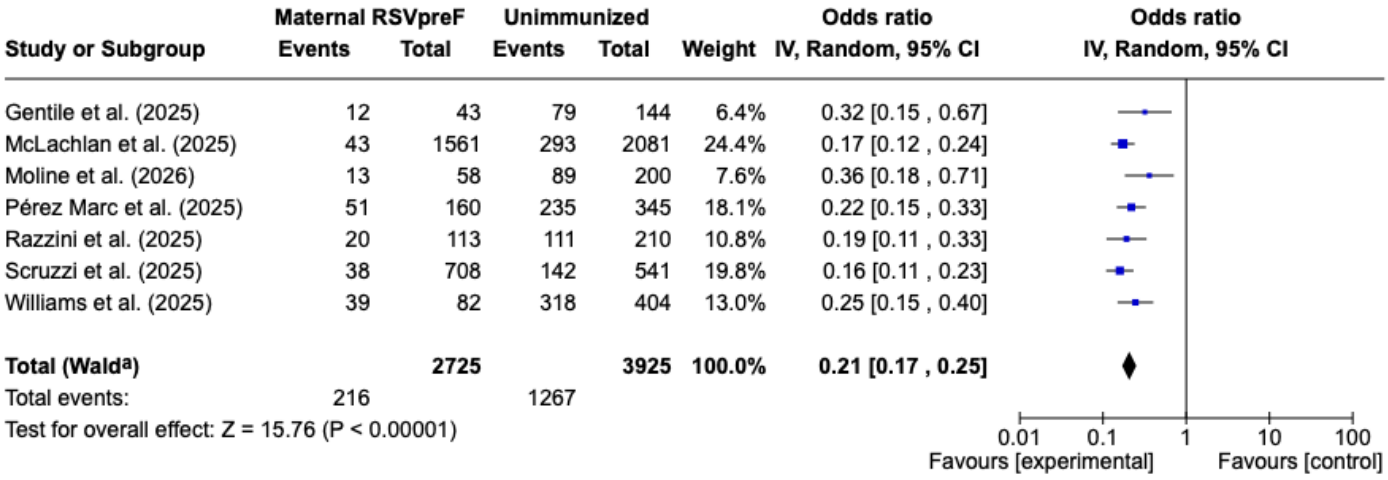
Medically attended RSV-related LRTD/LRTI outcomes

Only one study reported effectiveness of the maternal RSVpreF vaccine against medically attended RSV-related outcomes. Moline (2025) reported maternal VE against medically attended RSV-associated ARI of 64% (95% CI 37.0–79.0).(16)

RSV-related hospitalization

Seven studies were pooled in the meta-analysis evaluating the effectiveness of maternal RSVpreF vaccination against RSV-related hospitalization (Figure 6). When data from all studies were combined (n=7; 2,725 in the maternal RSVpreF group and 3,925 in the unimmunized group), maternal RSVpreF vaccination was associated with a reduction in the odds of RSV-related hospitalization (OR 0.21, 95% CI 0.17–0.25), corresponding to a 79% effectiveness (95% CI 75.0–83.0), with low heterogeneity (τ^2=0.01; I^2=19%).

Figure 6: Effectiveness of Maternal vaccine against RSV-related hospitalization among infants and children <2 years)



Heterogeneity: Tau² (DL[b], 95% CI) = 0.01 [0.00 , 0.37]; Chi² = 7.40, df = 6 (P = 0.29); I² = 19%

Footnotes

[a]CI calculated by Wald-type method.

[b]Tau² calculated by DerSimonian and Laird method.

RSV-related severe disease

Two studies reported effectiveness of the maternal RSVpreF vaccine against severe RSV-related outcomes. Razzini (2025) reported maternal VE against PICU admission of 87.2% (95% CI 52.6–97.0).(17) Moline (2025) reported maternal VE against ICU admission of 90% (95% CI 68–97).(16)

Duration of protection

None of included studies reporting on the maternal RSVpreF vaccine (ABRYSVO™) include more than one explicit time-stratified follow-up period that would demonstrate long-term effectiveness, durability, or waning protection.

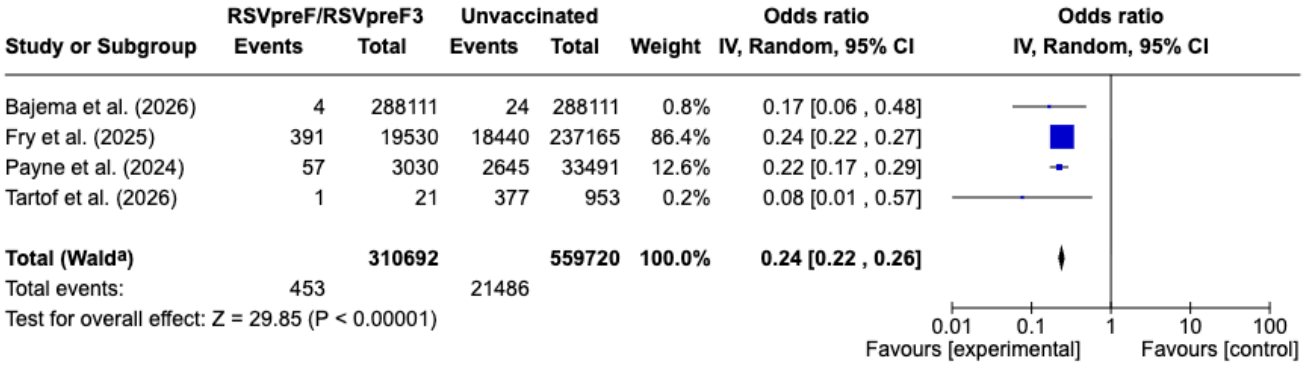
1.2 Older adults aged ≥60 years

1.2.1 RSVPreF3 vaccine (AREXVY™) and RSVpreF vaccine (ABRYSVO™)

Medically attended *RSV-related LRTD/LRTI outcomes*

Four studies were pooled in the meta-analysis evaluating the effectiveness of RSVpreF and RSVpreF3 vaccines against RSV-related emergency department visits (Figure 7). When data from all studies were combined (n=4; 310,692 in the RSVpreF/RSVpreF3 group and 559,720 in the unvaccinated group), RSVpreF/RSVpreF3 vaccination was associated with a reduction in the odds of RSV-related emergency department visits (OR 0.24, 95% CI 0.22–0.26), corresponding to a 76% effectiveness (95% CI 74.0–78.0), with no observed heterogeneity (τ^2=0.00; I^2=0%).

Figure 7: Effectiveness of RSVPreF3/RSVpreF vaccine against RSV-related related LRTD/LRTI among older adults aged ≥60 years



Heterogeneity: Tau² (DL[b], 95% CI) = 0.00 [0.00 , 3.15]; Chi² = 1.99, df = 3 (P = 0.57); I² = 0%

Footnotes

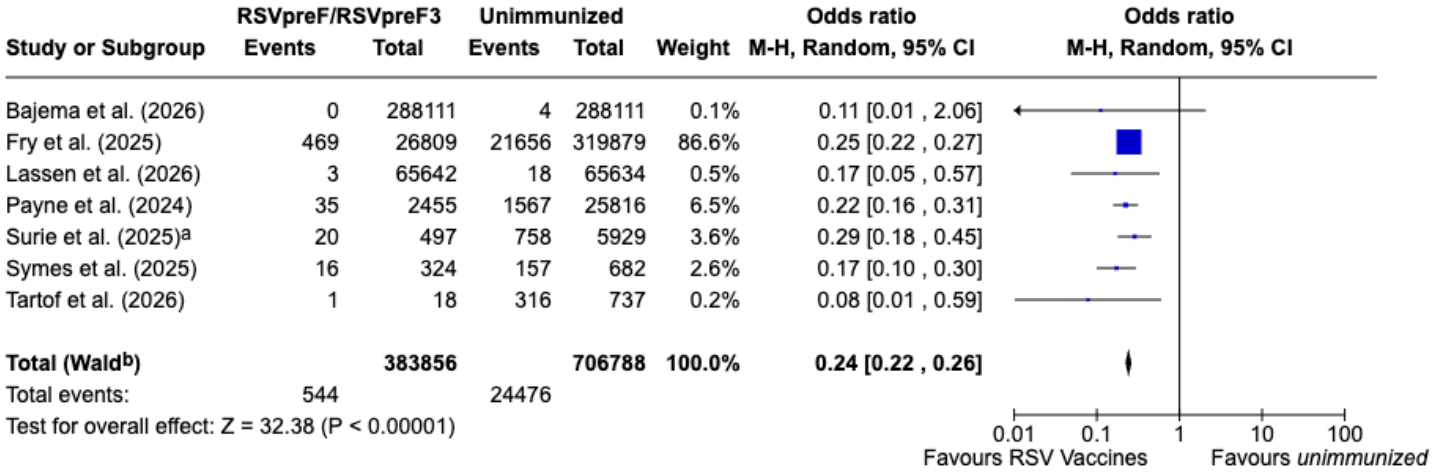
[a]CI calculated by Wald-type method.

[b]Tau² calculated by DerSimonian and Laird method.

RSV-related hospitalization

Seven studies were pooled in the meta-analysis evaluating the effectiveness of RSVpreF and RSVpreF3 vaccines against RSV-related hospitalization (Figure 8). When data from all studies were combined (n=7; 383,856 in the RSVpreF/RSVpreF3 group and 706,788 in the unimmunized group), RSVpreF/RSVpreF3 vaccination was associated with a reduction in the odds of RSV-related hospitalization (OR 0.24, 95% CI 0.22–0.26), corresponding to a 76% effectiveness (95% CI 74.0–78.0), with no observed heterogeneity (τ^2=0.00; I^2=0%). Of note, 0.3% of the vaccinated group in Surie et al. (2025) were vaccinated with mRESVIA.(18)

Figure 8: Effectiveness of RSVPreF3/RSVpreF vaccine against RSV-related hospitalization among older adults aged ≥60 years



Heterogeneity: Tau² (DL[c], 95% CI) = 0.00 [0.00 , 0.39]; Chi² = 4.12, df = 6 (P = 0.66); I² = 0%

Footnotes

[a]0.3% of the vaccinated group were vaccinated with mRESVIA

[b]CI calculated by Wald-type method.

[c]Tau² calculated by DerSimonian and Laird method.

RSV-related severe disease

Due to variability in the definitions of severe disease across studies, these data were not pooled in a meta-analysis. Three studies reported vaccine effectiveness (VE) of RSV protein subunit vaccines (RSVpreF and/or RSVpreF3) against RSV-associated severe disease outcomes in adults aged ≥60 years, though the definitions of severity varied across studies. Tartof 2026 reported VE of 92% (95% CI 35.0–99.0) against severe RSV-associated acute respiratory illness requiring oxygen supplementation, and 90% (95% CI 16.0–99.0) against a composite of critical outcomes including ICU admission, mechanical ventilation, respiratory failure, vasopressor use, or death, among adults aged ≥60 years during the 2023–2024 season.(19) Payne 2024, using the VISION network across eight US states during the same 2023–2024 season, reported VE of 81% (95% CI 52.0–92.0) against RSV-associated critical illness, defined as ICU admission or in-hospital death, among immunocompetent adults aged ≥60 years.(20) Symes 2025 estimated VE against RSV-associated severe disease, defined as hospital admission requiring oxygen supplementation, high-flow nasal oxygen, non-invasive ventilation or continuous positive airway pressure, invasive mechanical ventilation, ICU admission, or death within 30 days, at 86.7% (95% CI 75.4–93.6).(21) Surie 2025, spanning two RSV seasons, reported VE against severe in-hospital outcomes over both seasons combined: 67% (95% CI 53.0–77.0) against supplemental oxygen requirement, 73% (95% CI 50–86.0) against acute respiratory failure, 73% (95% CI 49.0–86.0) against acute organ failure, 67% (95% CI 37.0–83.0) against ICU admission, and 72% (95% CI 7.0–91.0) against invasive mechanical ventilation or death. These estimates were lower than those from first-season studies.(18)

Duration of protection

Payne et al. (2024), evaluating the first RSV season in the VISION network, reported patterns suggesting possible early within-season waning among immunocompetent adults, although confidence intervals overlapped.(20) Vaccine effectiveness against RSV-associated hospitalization was 90% (95% CI 79–95) at 14–59 days post-vaccination and 73% (95% CI 60.0–82.0) at ≥60 days. A similar pattern was observed for emergency department encounters, declining from 85% (95% CI 77.0–91.0) to 70% (95% CI 58.0–78.0).(20)

Surie et al. (2025), using a test-negative case-control design enrolling adults aged ≥60 years hospitalized with acute respiratory illness across two RSV seasons (2023–2024 and 2024–2025) at 26 US hospitals, reported evidence of waning protection against RSV-associated hospitalization over time.(18) When stratified by timing of the single vaccine dose relative to illness onset, effectiveness against RSV-associated vaccination (48%; 95% CI 27–63), although this difference did not reach statistical significance (p = .06). Waning was more pronounced among immunocompromised adults, for whom effectiveness declined from 54% (95% CI −2.0 to 79.0) with same-season vaccination to 11% (95% CI −51.0 to 48.0) with prior-season vaccination, compared with immunocompetent adults, among whom effectiveness declined from 74% (95% CI 53–85) to 62% (95% CI 40–76). Product-specific estimates were similar: 64% (95% CI 47.0–76.0) for RSVPreF3 and 61% (95% CI 41.0–74.0) for RSVpreF during two seasons.(18)

Extending follow-up further, Bajema et al. (2026) provided the most granular longitudinal evidence, following 288,111 vaccinated U.S. veterans over a median of 15.8 months. Effectiveness against hospitalization declined from 88.9% (95% CI 77.9–95.7) at 0–1 month to 57.3% (95% CI 47.3–66.4) at 18 months, and against ICU admission from 92.5% (95% CI 61.1–100.0) to 71.9% (95% CI 42.8–90.0). Waning was most pronounced among immunocompromised individuals, for whom effectiveness against documented infection declined from 75.2% (95% CI 52.5–89.3) to 39.7% (95% CI 23.9–52.7), compared with a decline from 83.9% (95% CI 78.1–88.8) to 60.7% (95% CI 56.2–65.2) among non-immunocompromised individuals. At 18 months, effectiveness remained broadly comparable between products: 55.9% (95% CI 51.0–61.2) for RSVpreF and 64.6% (95% CI 57.1–71.8) for RSVPreF3.(22)

1.2.2 mRESVIA™

None of the included studies examined the effectiveness of mRESVIA vaccine against RSV-related outcomes.

2. Efficacy of RSV immunization products

All content in Section 2 (subsections 2.1 through 2.3) and Table 2 is retained unchanged from RES 127. This includes: 2.1.1 Nirsevimab efficacy in infants, 2.1.2 Maternal RSVpreF vaccine efficacy, 2.2.1 RSVPreF3 (AREXVY) efficacy in older adults, 2.2.2 RSVpreF (ABRYSVO) efficacy in older adults, 2.2.3 mRESVIA efficacy, and 2.3 Adults aged 18–50 years challenge study. No text changes are provided in this section as compared to the first version of the report.

2.1 Infants and children aged <2 years

2.1.1 Nirsevimab monoclonal antibody (BEYFORTUS™)

Multiple randomized, double-blind, placebo-controlled trials have demonstrated the efficacy of nirsevimab in preventing RSV-related infections in infants. Simões (2023) conducted a comprehensive evaluation of nirsevimab efficacy, reporting a 79.5% relative risk reduction (95% CI 65.9–87.7) for the primary endpoint of medically attended RSV-related LRTD/LRTI. The study also demonstrated a 41.9% relative risk reduction (95% CI 25.7–54.6) for LRTI/LRTD outpatient visits.(23) Similarly, Griffin (2020) focused on preterm infants with gestational age at birth of 29 weeks 0 days to 34 weeks 6 days, showing a 70.1% lower incidence (95% CI 52.3–81.2, p<0.001) of medically attended RSV-related LRTI/LRTD compared to placebo.(24)

For RSV-related LRTI/LRTD requiring hospitalization, Simões found a 77.3% relative risk reduction (95% CI 50.3–89.7) and Griffin demonstrated a 78.4% lower incidence (95% CI 51.9–90.3) compared to placebo.(23; 24) Drysdale (2023) conducted a pragmatic, phase 3b, open-label, two-group, randomized trial across 235 sites in France, Germany, and the United Kingdom that included healthy infants 12 months or younger born at gestational age ≥29 weeks. This study reported an 83.2% efficacy (95% CI 67.8–92.0, p<0.001) for RSV-related LRTD/LRTI hospitalization. Country-specific efficacy against hospitalization for RSV-related LRTD/LRTI in the Drysdale study showed consistent results across regions: France (89.6%, adjusted 95% CI 58.8–98.7), Germany (74.2%, adjusted 95% CI 27.9-92.5), and United Kingdom (83.4%, adjusted 95% CI 34.3–97.6).(25)

Regarding severe RSV-related LRTI/LRTD, Simões (2023) reported an 86.0% relative risk reduction (95% CI 62.5–94.8).(23) Drysdale (2023) reported an efficacy of 75.7% (95% CI 32.8–92.9, p=0.004) with 5 infants (0.1%) in the nirsevimab group versus 19 infants (0.5%) in the standard-care group.(25)

2.1.2 Maternal RSVpreF vaccine (ABRYSVO™) and Maternal RSVPreF3 vaccine

Several randomized, double-blind, placebo-controlled trials have demonstrated the efficacy of maternal RSVpreF vaccine in preventing RSV infections in infants. For medically attended RSV-related LRTD/LRTI. Kampmann (2023) reported 57.1% efficacy (99.5% CI 14.7–79.8) within 90 days after birth and 51.3% efficacy (97.58% CI 29.4–66.8) within 180 days after birth in the MATISSE trial, which included 7,358 pregnant women at 24–36 weeks' gestation across 18 countries, with 3,570 infants whose mothers received RSVpreF and 3,558 infants whose mothers received placebo.(26)

Dieussaert (2024) reported 65.5% efficacy (95% CI 37.5–82.0) for any medically assessed RSV-related LRTI/LRTD from birth to 6 months of age in a phase 3 trial of maternal RSVPreF3-Mat (by GlaxoSmithKline) that included 5,328 pregnant women with 3,426 infants in the vaccinated group and 1,711 in the placebo group.(27) However, it is important to note that this vaccine is not approved for use, and enrollment and vaccination were stopped prematurely due to a higher risk of preterm birth observed in the vaccine group compared to the placebo group.

Regarding RSV-related hospitalization, Kampmann (2023) showed 67.7% efficacy (99.17% CI 15.9-89.5) within 90 days after birth and 56.8% efficacy (99.17% CI 10.1–80.7) within 180 days after birth.(26)

For severe medically attended RSV-related LRTI/LRTD, Kampmann (2023) reported 81.8% efficacy (99.5% CI 40.6-96.3) within 90 days after birth and 69.4% efficacy (97.58% CI 44.3–84.1) within 180 days after birth.(26) Dieussaert (2024) reported 69.0% efficacy (95% CI 33.0–87.6) for severe medically assessed RSV-associated LRTD.(27)

2.2 Older adults aged ≥60 years

2.2.1 RSVPreF3 vaccine (AREXVY™)

Multiple phase 3 trials have been conducted to evaluate the efficacy of RSVPreF3 vaccine in adults ≥60 years. For RSV-related LRTI/LRTD, Curran (2024) showed 87.5% efficacy (95% CI 58.9–97.6) against RSV-confirmed LRTI/LRTD with medically attended visits in an observer-blind, multi-country, randomized trial.(28) Ison (2024) reported 67.2% efficacy (97.5% CI 48.2–80.0) for one dose over 2 RSV seasons in the AReSVi-006 phase 3 trial conducted across 17 countries.(9) For severe RSV-related LRTD, Ison (2024) reported 78.8% efficacy (95% CI 52.6–92.0%) for one dose over 2 RSV seasons.(9)

Regarding RSV-related ARI, Curran (2024) showed 79.0% efficacy (95% CI 54.3–91.5) against RSV-confirmed ARI with medically attended visits.(28) Ison (2024) showed 52.7% efficacy (95% CI 40.0–63.0) for one dose over 2 RSV seasons.(9)

2.2.2 RSVpreF vaccine (ABRYSVO™)

The RSVpreF (ABRYSVO™) vaccine by Pfizer demonstrated efficacy in older adults across several trials. For RSV-related LRTI/LRTD with ≥2 signs or symptoms, Walsh (2024) reported pooled data across two seasons showing 58.8% efficacy (95% CI 43.0–70.6). For RSV-related LRTI/LRTD with ≥3 signs or symptoms, Walsh (2024) reported 85.7% efficacy (96.66% CI 32.0–98.7) across two seasons combined.(11) For RSV-associated ARI, Walsh (2024) reported 62.1% efficacy (95% CI 37.1–77.9) across two seasons combined.(11)

2.2.3 mRESVIA™

Wilson (2023) evaluated the mRNA-1345 vaccine (mRESVIA™) in the ConquerRSV trial, a randomized, double-blind, placebo-controlled phase 2–3 trial that included 35,541 participants aged 60 years and older. For RSV-related LRTI/LRTD ≥2 signs or symptoms, the study found 83.7% efficacy (95.88% CI 66.0–92.2, one-sided P<0.001). For RSV-related LRTI/LRTD with ≥3 signs or symptoms, the efficacy was 82.4% (96.36% CI 34.8–95.3, one-sided P = 0.008). For RSV-related ARI, the study showed 68.4% efficacy (95% CI 50.9–79.7).(29)

2.3 Adults aged 18–50 years

In a challenge study, Schmoele-Thoma (2022) evaluated a bivalent prefusion F RSV vaccine (RSVpreF) in 70 healthy adults aged 18–50 years with low baseline RSV-neutralizing antibody titers and showed 86.7% efficacy (95% CI 53.8–96.5) against symptomatic RSV infection confirmed by any detectable viral RNA, and 100.0% efficacy (95% CI 72.8–100.0) against symptomatic RSV infection confirmed by quantifiable RT-qPCR or culture in a phase 2a, randomized, double-blind study.(30)

Next steps based on the identified evidence

The following recommended actions, synthesized from those identified in our comprehensive review of the evidence, address critical knowledge gaps in RSV vaccine and monoclonal antibodies effectiveness. They provide a structured framework to enhance research and public-health responses to seasonal RSV outbreaks. These recommendations aim to strengthen our understanding of vaccine performance across different populations while improving outbreak management strategies.

- Research recommendations from included studies
  - **Address evidence gaps** in maternal RSVpreF vaccine effectiveness by conducting real-world studies focused on infant outcomes (0–6 months) and as the current evidence base is limited to seven studies for hospitalization, a single study for medically attended RSV outcomes, and no time-stratified data to assess duration of protection.
  - Evaluate mRESVIA's and clesrovimab's effectiveness in their respective target populations, as no included studies examined either product, leaving a complete gap in real-world evidence for two licensed RSV prevention options that may be incorporated into immunization programs.

- **Investigate duration of protection** through extended follow-up studies, particularly focusing on protection beyond 14 weeks for nirsevimab in infants, where effectiveness against medically attended infection declined from approximately 76% to 55%, and beyond 18 months for adult RSV vaccines, where effectiveness against hospitalization declined from 89% to 57%, with more pronounced waning among immunocompromised individuals.

- Policy implications
  - **Design and implement vaccination strategies** for nirsevimab programs focusing on protecting young infants under two years of age, where the evidence shows strongest protection against severe RSV disease requiring hospitalization ICU admission and respiratory support across a large body of evidence.
  - **Establish surveillance systems** to monitor real-world effectiveness across different populations, geographic regions, and RSV seasons, particularly given that the majority of current evidence comes from a limited number of high-income countries, with limited data from low- and middle-income settings where RSV burden is highest.
  - **Consider seasonal timing of immunization** for older adults receiving RSV vaccines, given the evidence of waning protection over time, with notably lower effectiveness when vaccination occurred in a prior season compared with the current season, to ensure optimal coverage during peak RSV activity periods.
  - **Develop tailored immunization strategies** for immunocompromised populations, where evidence consistently demonstrates more pronounced waning of protection compared with non-immunocompromised individuals across multiple outcomes and time points.

Table 1: Characteristics of all included studies reporting on the effectiveness of RSV immunization products

Reference (author year) with URL	Research question addressed	Geographical location	Design and Study Period	Population	Analysis	Type of immunization product
Ares-Gómez 2024 (31)	• Effectiveness of nirsevimab against RSV-related lower respiratory tract infection (LRTI) hospitalizations and severe RSV-related LRTI requiring oxygen support in infants	Galicia, Spain	Design: Longitudinal study Study period: 25 September 2023–31 March 2024	Participants included 10,259 infants (0 to 2 years old) eligible for nirsevimab, with 9,408 (91.7%) receiving the immunization and 851 (8.3%) not receiving nirsevimab	Nirsevimab effectiveness was estimated using Poisson regression models with robust variance, adjusted for enrollment group (seasonal or catch-up), sex, and residential area, with Cox proportional hazards models used as a secondary analysis for confirmation	• Monoclonal antibody BEYFORTUS ™ (nirsevimab) by Sanofi
Estrella-Porter 2024 (32)	• Effectiveness of nirsevimab against hospitalizations for cases with RSV	Spain	Design: Observational retrospective study Study period: 1 October 2023–31 March 2024	Participants included 27,362 children (0–2 years old) eligible for the nirsevimab, with 24,223 vaccinated	Nirsevimab effectiveness was calculated using multivariate logistic regression, controlling for factors such as breastfeeding intention, mother's country of origin, gestational weeks, and campaign group, to derive an adjusted odds ratio comparing RSV infection rates between immunized and non-immunized infants	• Monoclonal antibody BEYFORTUS ™ (nirsevimab) by Sanofi
Ezpeleta 2024 (33)	• Effectiveness of nirsevimab against hospitalizations for cases with RSV, RSV-related emergency department (ED) consultations, and RSV-related ICU admissions	Spain	Design: Population based study, prospective cohort design Study period: July 2023–January 2024	Participants included 1,177 infants (0–2 years old), 1,083 had received a vaccine receiving the vaccine seven days after birth	Epidemiological surveillance, assessing nirsevimab effectiveness and relative risk Hospitalization rates were confirmed using Cox regression adjusted for sex and week of birth, with nirsevimab immunization as a time-dependent variable, estimating effectiveness as (1 – hazard ratio) x 100 for various RSV-related outcomes	• Monoclonal antibody BEYFORTUS ™ (nirsevimab) by Sanofi
Moline 2024 (34)	• Nirsevimab Effectiveness against infection and hospitalization	United States	Design: Test-negative case-control design Study period: 1 October 2023–29 February 2024	A total of 699 infants (0–2 years old) were included in the study	Pearson's chi-square was used to compare demographic questionnaire by vaccine status. Multivariate logistic regression was used to estimate vaccine effectiveness	• Monoclonal antibody BEYFORTUS ™ (nirsevimab) by Sanofi

Reference (author year) with URL	Research question addressed	Geographical location	Design and Study Period	Population	Analysis	Type of immunization product
López-Lacort 2024 (35)	• Effectiveness of nirsevimab on infection and lower respiratory tract infection	Spain	Design: Test-negative design Study period: October 2023 to January 2024	A total of 15,676 infants (0–2 years old) were eligible for this study	Bayesian logistic regression was used and supported by a sensitivity analysis to estimate vaccine effectiveness	• Monoclonal antibody BEYFORTUS ™ (nirsevimab) by Sanofi
Lassoued 2024 (36)	• Effectiveness of nirsevimab against RSV-positive bronchiolitis	France	Design: Test-negative case-control study Study period: 15 September 2023–1 February 2024	A total of 883 infants (0–12 months) were included in the study	Multivariate logistic regression estimated nirsevimab effectiveness; subgroup analyses were performed based on infant's age and gestational age at birth	• Monoclonal antibody BEYFORTUS ™ (nirsevimab) by Sanofi
Assad 2024 (37)	• Effectiveness of nirsevimab against hospitalization for RSV-positive bronchiolitis	France	Design: Prospective matched case-control study Study period: 15 October 2023–10 December 2023	1,035 patients (690 cases, 345 controls; aged <12 months); 157 (15.2%) were immunized with nirsevimab (60 case patients, 97controls)	A conditional logistic-regression model and a multivariate regression model estimate nirsevimab effectiveness; subgroup analyses were performed based on infant's age, pediatric intensive care unit (PICU) admission, ventilatory support, and at least one risk factor for severe bronchiolitis	• Monoclonal antibody BEYFORTUS ™ (nirsevimab) by Sanofi
Agüera 2024 (31)	• Nirsevimab effectiveness against hospitalization for RSV-associated bronchiolitis and severe RSV disease, Bronchiolitis Score of Sant Joan de Déu, need for oxygen support, and length of hospital stay in children younger than 12 months	Spain and Andorra	Design: Test-negative case-control Study period: November 2023–February 2024	234 children (up to 12 months old), 141 cases and 93 controls; 181 patients were eligible for nirsevimab; 109 (46.6%) patients had received nirsevimab, 72 (30.8%) were eligible but had not been immunized, and 53 (22.6%) were not eligible	Multivariate analysis using a logistic regression model adjusted for age, weight, and presence of one or more preexisting conditions was used to estimate nirsevimab effectiveness; subgroup analyses were performed by age and presence of comorbidities	• Monoclonal antibody BEYFORTUS ™ (nirsevimab) by Sanofi
Coma 2024 (38)	• Effectiveness of nirsevimab against primary care attended bronchiolitis, RSV infection, viral pneumonia diagnosed in primary care, ED visits due to bronchiolitis, RSV-related hospitalization, and RSV-	Spain	Design: Retrospective cohort study Study period: 1 October 2023–31 January 2024	26,525 infants (0–6 months old) born between April and September 2023; 23,127 (87.2%) had received nirsevimab	The Kaplan-Meier estimator and Cox regression models were used to evaluate nirsevimab effectiveness; the analysis was adjusted for age at beginning of study, sex, area of residence, nationality, rurality, and socioeconomic status; a final Cox regression model stratified by months of birth was performed	• Monoclonal antibody BEYFORTUS ™ (nirsevimab) by Sanofi

Reference (author year) with URL	Research question addressed	Geographical location	Design and Study Period	Population	Analysis	Type of immunization product
	related ICU admission in infants born between April and September 2023					
Paireau 2024 (39)	• Effectiveness of nirsevimab against PICU hospitalization for RSV-associated bronchiolitis in infants <5 months old (or <9 months old if they had comorbidities)	France	Design: Test-negative case-control Study period: 15 September 2023–31 January 2024	288 infants (0–9 months old, 238 cases and 50 controls), 58 (20%) had received nirsevimab prior to treatment in the paediatric intensive care unit (PICU)	A logistic regression model was used to estimate the nirsevimab effectiveness on hospitalization to PICU for RSV-bronchiolitis in infants, adjusting for age group, sex, presence of comorbidities, prematurity, and time period	• Monoclonal antibody BEYFORTUS ™ (nirsevimab) by Sanofi
Barbas Del Buey 2024 (14)	• Effectiveness of nirsevimab against hospitalization, ICU admission, ED care, and medically attended bronchiolitis/bronchitis for infants aged 0–10 months old	Spain	Design: Prospective cohort study Study period: 1 October 2023–29 February 2024	37,067 (80.8% immunized) infants (0 to ten months old) born between April and December 2023 were included in the population eligible for immunization; 33,859 were included in the analysis of nirsevimab effectiveness	A multivariable Cox regression model was used to estimate the effectiveness of nirsevimab. The model was adjusted for the following variables: sex, age, gestational age at birth, type of gestation, presence of comorbidities, net income of household, cumulative incidence of RSV infection in children aged 0–5 years old in the area of residence, and epidemiological week	• Monoclonal antibody BEYFORTUS ™ (nirsevimab) by Sanofi
Xu, 2025 (previously preprint) (13)	• Effectiveness of nirsevimab against medically attended RSV infection, hospitalization, outpatient visits, severe RSV, all-cause LRTI, all-cause LRTI hospitalization, and RSV-associated LRTI	Study Design: Multicentre, case-control, test-negative study Study Period: October 1, 2023 through May 9, 2024	The study population included infants born after October 1, 2022, who were tested for RSV due to suspected acute respiratory infection (ARI) and received care within the Yale New Haven Health System between October 1, 2023 and May 9, 2024. RSV testing was performed using nasopharyngeal polymerase chain reaction (PCR)	Vaccine effectiveness (VE) was estimated using a test-negative design. Odds ratios (ORs) for prior nirsevimab receipt among RSV-positive cases versus RSV-negative controls were calculated using multivariable logistic regression. VE was computed as: VE = (1 − OR) × 100%	Study Design: Multicentre, case-control, test-negative study Study Period: October 1, 2023 through May 9, 2024	• Monoclonal antibody BEYFORTUS ™ (nirsevimab) by Sanofi
López-Lacort 2025 (40)	• Effectiveness of nirsevimab in preventing RSV-LRTI in overall and	Spain	Design: Test-negative design (TND)	160 infants (0 to <10 months old); 141 infants (88%) received nirsevimab; 29 infants (21%) was administered in	A Bayesian logistic regression model was used to analyze the effectiveness of nirsevimab in preventing RSV-LRTI	• Monoclonal antibody BEYFORTUS

Reference (author year) with URL	Research question addressed	Geographical location	Design and Study Period	Population	Analysis	Type of immunization product
	catch-up infants <10 months old		Study period: November 1, 2023 [week 45], and February 29, 2024	hospital and 112 (79%) administered to catch-up group (targeted effort outside of hospital administration)	in infants <20 months of age (both overall and for catch-up infants); effectiveness was calculated using (1 – Odds Ratio) x 100% and random effects was calculated to account for primary care center variability; non-informative priors were also set for model parameters to avoid bias on estimations	™ (nirsevimab) by Sanofi
Carbajal 2024 (41)	• Effectiveness of nirsevimab in reducing paediatric emergency department visits, ICU admissions, hospitalizations and severe RSV-bronchiolitis for all-cause bronchiolitis and RSV-associated bronchiolitis	France	Design: Case-control study Study period: 14 October 2023–29 February 2024	2,786 infants (0–12 months old, 864 case infants diagnosed with bronchiolitis, 1,922 control infants without bronchiolitis); 178 (21%) case infants had received nirsevimab, 686 (79%) had not received Of 864 infants diagnosed with bronchiolitis, 277 (32%) were RSV PCR tested; of the 67 infants tested for RSV who had received nirsevimab, 22 (33%) tested positive	The effectiveness of nirsevimab in reducing ED visits was calculated using odds ratio ((1– Odds Ratio) x 100%) adjusted for week of ED visit, sex, and age; sensitivity analyses were also conducted including logistic regression analysis with age as a continuous variable; a Bayesian logistic model was used to predict RSV status in infants who did not undergo PCR sampling	• Monoclonal antibody BEYFORTUS ™ (nirsevimab) by Sanofi
Rodríguez-Fernández 2024 (42)	• Effectiveness of nirsevimab against hospitalization	Spain	Design: Case-control study Study period: 1 September 2015–31 December 2023	138 infants (<6 months old), 32 admitted for bronchiolitis (21 with RSV bronchiolitis); of the 21 admitted for RSV bronchiolitis 6 (28%) had received nirsevimab. Of the 11 admitted for bronchiolitis due to another cause 8 (72%) received nirsevimab	The effectiveness of nirsevimab in reducing hospitalization was calculated using (1– Odds Ratio) x 100%; Sensitivity Analyses were also performed to compare seasons with lower RSV and other factors	• Monoclonal antibody BEYFORTUS ™ (nirsevimab) by Sanofi
Tartof 2024 (43)	• Respiratory Synctial Virus Prefusion F effectiveness in older adults	California, United States	Design: Retrospective case-control study and test-negative design Study period: May–September 2024	A total of 10 566 patients, 60 years or older, who had LRTD hospitalizations or emergency department encounters; approximately 76.5% of participants had a nasal swab, 60.7% were tested for RSV, and 64.2% of participants were included in the final analysis	Vaccine effectiveness was assessed using 1 – Odds Ratio x 100%; the 95% confidence interval was reported; a multivariate logistic regression was used	• RSVpreF (Abrysvo)
Rius-Peris 2025 (44)	• Effectiveness of the impact of nirsevimab immunisation on acute bronchiolitis hospitalizations during	Spain	Design: Test-negative case-control study	A total of 2,656 patients were ultimately included in the study, of whom 61.26% were male, with a median age of 2.6 months (interquartile range 1.5 to 5.0 months).	Infants who tested positive for RSV by polymerase chain reaction were classified as cases, while those who tested negative served as controls. Effectiveness was calculated as (1 −	• Monoclonal antibody BEYFORTUS ™

Reference (author year) with URL	Research question addressed	Geographical location	Design and Study Period	Population	Analysis	Type of immunization product
	nearly the entire 2023–2024 epidemic year		Study period: 1 September 2021 to 15 June 2024	Overall, 13.37% had underlying health conditions, most commonly prematurity (10.17%). Infants at 0 to 12 months old.	OR) × 100%, where the odds ratio (OR) reflects the likelihood of having received nirsevimab among cases compared with controls.	(nirsevimab) by Sanofi
Moline 2025 (16)	• Compare the epidemiology and disease burden of RSV-associated acute respiratory illness in children younger than 5 years	United States	Design: Case-control study Study period: RSV seasons (September to April), 2017–2020	A total of 28,689 children younger than 5 years, with medically attended acute respiratory illness participated in this study; medically attended was defined as a visit to urgent care, emergency department, or hospitalization	The effectiveness of nirsevimab was estimated using a test-negative design and multivariable logistic regression model; site, age, months of enrollment, and presence of a high-risk medical condition was accounted for in the model Effectiveness was calculated using (1 – adjusted odds ratio) x 100% Hospitalization incidence rates were calculated per 1,000 participants with a 95% bootstrap percentile confidence interval	• Nirsevimab
Pérez Marc 2025 (45)	• Evalute RSVpreF vaccine effectiveness during pregnancy against infant RSV-related LRTD and severe LRTD hospitalizations within the first 6 months of life	Argentina	Design: Multicentre, retrospective, test-negative, case-control study NCT06647654 Study period: 1 April 2024 to 30 September 2024	Across 12 hospitals, 633 infants aged ≤6 months were hospitalised for LRTD between April 1 and Sept 30, 2024, with 585 meeting eligibility criteria. After exclusions, 505 infants were included in the main analysis, with hospital contributions ranging from 9 to 114 cases. Among these, 286 (57%) were RSV-positive (cases) and 219 (43%) were RSV-negative (controls). The average age at hospitalization was similar between groups, and most infants were ≤4 months old	Adjusted vaccine effectiveness against RSV-related LRTD and severe LRTD hospitalizations (up to 6 months of age) was estimated using multilevel logistic regression with inverse probability-of-treatment weighting (IPTW) and additional covariate adjustment to control for confounding. Models also adjusted for hospitalization date and infant age, with further variables included if imbalance remained. Vaccine effectiveness was calculated as (1 − adjusted OR) × 100	• Nirsevimab
Lefferts 2024 (46)	• Effectiveness of nirsevimab against RSV-related medically attended acute respiratory illness and hospitalization in children in their first and second RSV seasons	United States	Design: Test-negative case-control Study period: October 2023–June 2024	472 children aged <20 months on 1 October 2023 or born after that date; 48% of included patients had received nirsevimab	Odds ratios of medically attended acute respiratory illness (ARI) associated with RSV was evaluated using multivariable logistic regression adjusted for age, sex, calendar month, residence community type, and presence of underlying conditions; effectiveness of nirsevimab was	• Monoclonal antibody BEYFORTUS ™ (nirsevimab) by Sanofi

Reference (author year) with URL	Research question addressed	Geographical location	Design and Study Period	Population	Analysis	Type of immunization product
					estimated as (1 – adjusted odds ratio) x 100%	
Payne 2024 (20)	• A test-negative study assessing the effectiveness of RSV vaccination against hospitalization and emergency department encounters for adults ≥60 years.	United States	Design: Test-negative study Study period: 1 October 2023 to 31 March 2024	36,706 hospitalizations of patients ≥60 years old with RSV-like illness and RSV testing during the study period were identified, with 34,780 (95%) being linked to RSV-negative tests and 1,926 (5%) being linked to RSV-positive tests 37,842 emergency department patients ≥60 years old with RSV-like illness and RSV testing during the study period were identified, with 35,082 (93%) being linked to RSV negative tests and 2,760 (7%) being linked to RSV positive tests	Vaccine effectiveness (VE) against hospitalizations and emergency department encounters was measured by comparing the odds of vaccination among RSV-positive case patients and RSV-negative control patients	• RSVPreF3 (Arexvy, GSK) • RSVPreF (Abrysvo, Pfizer)
New studies included in 2026 January update						
Lassen 2026 (47)	• Vaccine effectiveness against hospitalization for RSV-related respiratory tract disease, respiratory tract disease from any cause, or cardio-respiratory disease in a large population of older adults in Denmark	Denmark	Design: Pragmatic, open-label parallel-group, randomized controlled, phase 4 trial Study period: November 2024 to 31 May 2025	This study included 131,276 intention-to-treat population, with 62,469 in the RSVpreF group and 62,458 in the control group	Vaccine effectiveness was calculated using incidence rate ratio to compare groups. 9% confidence intervals were constructed using the Clopper-Pearson model	• RSVpreF
Zambrano 2025 (48)	• Nirsevimab Effectiveness Against Intensive Care Unit Admission for Respiratory Syncytial Virus in Infants in the United States	United States	Design: Test-negative case-control Study period: December 1, 2024 – April 15, 2025	A total of 917 infants admitted to an ICU were enrolled, including 548 (60%) case-patients and 369 (40%) control patients. After the exclusion of 91 (17%) case-patients and 67 (18%) control patients, 457 case-patients and 302 control patients remained	Unconditional multivariable logistic regression was used to estimate odds ratios for the ICU admission and respiratory failure outcomes among the entire enrolled population, using generalized estimating equations to address within-hospital site correlation, and adjusting for infant age in months, biweekly date of hospital admission, U.S. Census Bureau region, the presence of one or more specified underlying medical conditions, and social vulnerability index of infant's residential zip code	• Nirsevimab

Reference (author year) with URL	Research question addressed	Geographical location	Design and Study Period	Population	Analysis	Type of immunization product
Vera-Punzano, 2025 (49)	• Effectiveness and impact of nirvesimab immunoprophilaxis against RSV related hospitalization in Navarra during two seasons (2023-2024, and 2024-2025)	Navarra, Spain	Design: Prospective cohort Study period: 1 October 2023 to 26 January 2025.	This study included 2699 newborns (1183 from the first season, 2023-2024, and 1516 from the second season, 2024-2025). 2541 (94,1%) received nirvesimab (1089, 95,8% in the first season, and 1452, 92,1% in the second season).	The Chi-squared or Fisher test was used to compare risk ratios between vaccinated and unvaccinated. Effectiveness of nirvesimab was estimated as (1 –Hazard Ratio) x 100. Hazard Ratios and 95% confidence intervals were estimated using a Cox regression model.	• Monoclonal antibody BEYFORTUS ™ (nirsevimab) by Sanofi
Tartof 2026 (19)	• Effectiveness of RSVpreF vaccine (Abrysso or Pfizer) against acute respiratory illness and severe disease in high risk persons	Southern, California	Design: Test-negative case control Study period: November 24, 2023 to April 9, 2024	Participants included 15 452 patients aged 60 years or older, with hospitalization visits at the study sites and whom received a nasal swab	Vaccine effectiveness (VE) was estimated using adjusted odds ratio and multivariate logistic regression	• RSVPreF (Abrysvo, Pfizer)
Hsiao 2025 (50)	• Effectiveness of BEYFORTUS™ (Nirsevimab) against RSV confirmation and RSV-associated healthcare utilization	Northern California	Design: Retrospective cohort study Study period: October 1, 2023, to April 30, 2024	This study focused on 31 900 infants in Northern California, 49% had received the Nirsevimab vaccine Mothers of all infants received prenatal care at the Northern California clinic. All infants were born at 37 or over weeks without any high-risk diagnoses	Vaccine effectiveness (VE) was estimated using adjusted cox regression analysis and adjusted hazard ratios	• BEYFORTUS ™ (nirsevimab)
Bermúdez-Barrezueta 2025 (51)	• Effectiveness of Nirsevimab administration on hospitalization and paediatric intensive care unit	Spain	Design: Observational study Study period: October 2023 and March 2024	This study focused on 311 children under five years of age receiving care at a tertiary hospital in Spain	Vaccine effectiveness (VE) was analyzed using a Kruskal-Wallis test	• BEYFORTUS ™ (nirsevimab)
Campos Mena 2025 (52)	• Effectiveness of the Nirsevimab vaccine on reducing RSV associated hospitalization in infants	Spain	Design: Test-negative case–control study design Study period: September 1 to October 1 2024	This study focused on children born between 1 April 2024 and 31 March 2025 and hospitalized with severe respiratory infection between 16 September and 1 October 2024	Vaccine effectiveness was analyzed using odds ratio and logistic regression	• Monoclonal antibody BEY FORTUS™ (ni rsevimab) by Sanofi
Scruzzi 2025 (53)	• Effectiveness of RSVpreF (Abrysvo®) against hospitalizations of children under six months of age	Spain	Design: Retrospective case-control study Study period:	This study included 1249 children (180 cases and 1069 controls) born between March 31 and October 31, 2024	Vaccine effectiveness was assessed using logistic regression and odds ratios	• RSVpreF (Abrysvo®)

Reference (author year) with URL	Research question addressed	Geographical location	Design and Study Period	Population	Analysis	Type of immunization product
			March 31 and October 31, 2024			
Razzini 2025 (17)	• Effectiveness of RSVpreF MI on RSV-related acute lower respiratory tract infections (ALRTI) hospitalizations and pediatric intensive care unit admissions	Argentina	Design: Multicentre, retrospective surveillance cohort study Study period: March 1 and November 9, 2024	This study included 8407 infants aged ≤18 months enrolled after being hospitalized with ALRTI	Comparisons between groups were conducted a Pearson's χ2 test. The impact of RSVpreF MI on hospitalizations was assessed using a Poisson regression model	• RSVpreF (Abrysvo®)
Consolati 2024 (54)	• Effectiveness of Nirsevimab vaccine on RSV bronchiolitis outcomes in children born during the 2023-204 epidemic season	Italy	Design: Prospective observational cohort study Study period: 1 May 2023 to 15 February 2024	This study included 556 infants born between 1 May 2023 and 15 February 2024	Differences between groups was completed using chi-square test	• Monoclonal antibody BEY FORTUS™ (nirsevimab) by Sanofi
Symes 2025 (21)	• Effectiveness of a bivalent RSV pre-F vaccine against RSV associated hospital admission in adults aged 75-79	England	Design: Multicentre, test-negative, case–control study Study period: Oct 1, 2024, and March 31, 2025	This study included 1006 older adults aged 75 to 79 who were admitted to hospital with acute respiratory infection	VE was calculated by subtracting VE-odds ratio, with a 95% CI	• ABRYSVO™ (RSVpreF) by Pfizer
McLachlan 2025 (55)	• Vaccine effectiveness of RSVpre-F vaccine against RSV-related LRTI hospitalization in infants in Scotland	Scotland	Design: Retrospective, nested case–control study Study period: August 12, 2024 and March 31, 2025	This study included 13,878 pregnant women who received the vaccine, accounting for 50% of those who were eligible.	Odds ratios and 95% confidence intervals were calculated to compare groups. Vaccine effectiveness was calculated using adjusted odds ratios.	• ABRYSVO™ (RSVpreF) by Pfizer
Godonou 2025 (56)	• Effectivness of RSVpreF in adults 60 years or older	United States	Design: Cohort study Study period: April 1, 2024, and Sept 30, 2024	This study included 281 participants (n=117 vaccinated) aged 60 or older	Vaccine effectiveness was estimated using a cox regression model	• ABRYSVO™ (RSVpreF) by Pfizer

Reference (author year) with URL	Research question addressed	Geographical location	Design and Study Period	Population	Analysis	Type of immunization product
Torres 2025 (57)	• Effectiveness of Nirsevimab against RSV-related ICU admissions and RSV-related LRTI hospitalizations in infants during the April 1, 2024, and Sept 30, 2024	Chile	Design: Retrospective cohort study Study period: April 1, 2024, and Sept 30, 2024	Data from 154173 infants was collected; 145087 infants received the vaccine and 9086 were not	Vaccine effectiveness was estimated using cox proportional hazards models and calculating the hazard ratio	• Monoclonal antibody BEY FORTUS™ (nirsevimab) by Sanofi
Fortunato 2025 (58)	• Effectiveness of Nirsevimab against hospitalization in infants during the 2024-2025	Southern Italy	Design: Test-negative case-control design Study period: January 1, 2024 and March 31, 2025	This study included 4280 infants born in Southern Italy, 54.7% of those whom received the Nirsevimab immunoprophylaxis vaccine.	VE was calculated using (PPI − PCI)/(PPI × (1 − PCI)) Odds ratio was calculated using (1 − odds ratio) × 100% Relative risk was calculated (1 − relative risk) × 100% Kruskal wallis was used to compare across groups	• Monoclonal antibody BEY FORTUS™ (nirsevimab) by Sanofi
Bajema 2026 (22)	• Effectiveness of RSVPreF3 on RSV infection, hospitalization, emergency department visit, and ICU admission in Veterans older than 60	United States	Design: Observational study Study period: September 2023 to March 2024	This study included 301 3000 Veterans 60 years or older who received the RSV vaccination and 288 111 matched controls	Incidence rates were calculated as the number of events per 1000 person-years, and 95% CIs. VE was estimated as 100 × (1 – risk ratio)	• AREXVY™ (RSVPreF3) by GlaxoSmithKline
Moline 2026 (59)	• Effectiveness of maternal RSV Nirsevimab vaccine against medically attended RSV-associated acute respiratory illness in children under the age of two	United States	Design: Test-negative case-control design Study period: October 1, 2024, to April 30, 2025	This study included 5029 children younger than two years of age with medically attended ARI	VE was calculated using adjusted odds ratio	• Monoclonal antibody BEY FORTUS™ (nirsevimab) by Sanofi
Costantino 2025 (54)	• Effectiveness of Nirsevimab against RSV infection in infants	Salerno, Italy	Design: Retrospective, monocentric, real-world pilot study Study period: November 2024 to April 2025	This study included 491 infants who were exposed to the Nirsevimab vaccine	Relative risk was calculated using the Katz log method Infection rates were calculated using two-sided Fisher exact tests	• Monoclonal antibody BEY FORTUS™ (nirsevimab) by Sanofi
Furgier 2025 (60)	• Effectiveness of Nirsevimab against RSV	France	Design: Test-negative case-control study	This study included 127 infants, 22% of which tested received the Nirsevimab vaccine	VE effectiveness was calculated a multivariate regression and the	• Monoclonal antibody BEY FORTUS™ (ni

Reference (author year) with URL	Research question addressed	Geographical location	Design and Study Period	Population	Analysis	Type of immunization product
	related hospitalization in infants		Study period: October 10, 2024 to March 15, 2025		equation: 100% × (1 − adjusted odds ratio)	rsevimab) by Sanofi
Coma 2025 (15)	• Effectiveness of Nirsevimab vaccine on hospitalization, primary care visits, and bronchiolitis	Catalonia, Spain	Design: Population-based retrospective cohort study Study period: April 2023 and March 2024	This study included 51154 infants, 89.9% of which received the Nirsevimab vaccine before or during their first RSV season	Cox proportional hazard models were used to calculated hazard ratios (HRs) and 95%CIs	• Monoclonal antibody BEY FORTUS™ (ni rsevimab) by Sanofi
Ma 2025 (61)	• Effectiveness of Nirsevimab vaccination against RSV infection in infants during the 2023-2024 season in the United States	United States	Design: Population-based cohort study Study period: October 1, 2023 to March 31, 2024	This study included 192677 infants who received the nirsevimab vaccination and 185625 who did not	A cox proportional hazards model was used to calculate hazard ratios with a 95% confidence interval	• Monoclonal antibody BEY FORTUS™ (ni rsevimab) by Sanofi
Kitano, 2025 (62)	• Effectiveness of nirsevimab against RSV infection beyond 6 months after administration in children under 24 months of age	North America	Design: Multi-centre retrospective cohort study Study period: July 1, 2023 – June 30, 2025 Database Accessed: October 20, 2025 (TriNetX)	4,627,861 children aged <24 months who underwent RSV nucleic acid testing between July 2023 and June 2025; 532 children had received nirsevimab prior to testing (stratified by time since administration), and 210,626 had not received nirsevimab	Vaccine effectiveness reported using odds ratios (ORs) with 95% confidence intervals (CIs) for RSV infection were estimated using the TriNetX platform. Subgroup analyses were conducted by epidemic period (October 2023 to April 2024; October 2024 to April 2025) and non-epidemic period (May 2024 to September 2024), with separate propensity score matching performed for each seasonal analysis. Vaccine effectiveness was approximated as (1 − OR) × 100%.	• Monoclonal antibody BEY FORTUS™ (ni rsevimab) by Sanofi
Gaio, 2025 (63)	• Effectiveness of nirsevimab in preventing RSV-related hospitalizations among children under 24 months during the 2023–2024 RSV season	Italy	Design: Retrospective test-negative case-control study	A total of 341 eligible children were included, with 40% (n=137) testing RSV-positive (cases) and 60% (n=204) testing RSV-negative (controls)	Odds ratios for RSV-positive hospitalization among children admitted with acute respiratory infection were estimated using multivariable logistic regression in a test-negative design. Vaccine effectiveness of nirsevimab was calculated as (1 − adjusted odds ratio) × 100%, with stratified analyses by	• Nirsevimab

Reference (author year) with URL	Research question addressed	Geographical location	Design and Study Period	Population	Analysis	Type of immunization product
					age group and time since immunisation.	
Fusco, 2025 (64)	• Effectiveness of nirsevimab in preventing RSV infection, RSV-associated hospitalization, and PICU admission among infants presenting to the Emergency Department with bronchiolitis during the first RSV season following its introduction into the Italian immunization program	Italy (Lombardy region, Milan)	Design: Retrospective test-negative case-control study Study Period: November 1, 2024 – March 31, 2025	Among the 208 infants included in the study, 76 (36.5%) tested positive for RSV and 132 (63.5%) tested negative. Overall, 58.2% of infants required hospitalization, and among those hospitalized, 11.7% required admission to the pediatric intensive care unit (PICU).	A test-negative case-control design was used, comparing RSV-positive bronchiolitis cases to RSV-negative controls. Odds ratios were calculated using unadjusted logistic regression, and vaccine effectiveness (VE) was estimated as (1 − odds ratio) × 100%. Separate analyses were conducted to estimate effectiveness against RSV infection, RSV-associated hospitalization, and PICU admission	• Nirsevimab
McLachlan, 2025 (55)	• Effectiveness of maternal RSVpreF vaccination, offered from 28 weeks' gestation, in preventing RSV-related lower respiratory tract infection hospitalizations in infants aged ≤90 days in Scotland	Scotland, United Kingdom	Design: Retrospective case-control study Study Period: August 12, 2024 - March 31, 2025	27,565 singleton live births in Scotland between August 12, 2024 and March 31, 2025. Among these, 50.2% (13,842/27,565) of pregnant women received maternal RSVpreF vaccination, 7.0% (1,940/27,565) were preterm births (<37 weeks), 354 infants aged ≤90 days were hospitalized with RSV-related LRTI, and 3,511 matched controls were included	VE was estimated primarily using a nested case–control design. Cases (infants ≤90 days hospitalized with RSV-related LRTI confirmed by PCR) were matched 1:10 to controls by ISO week of birth and gestational age at birth. VE was calculated as 100 × (1 − adjusted OR).	• RSVpreF (Abrysvo®, Pfizer)
Cocchi, 2025 (65)	• Effectiveness of nirsevimab prophylaxis on RSV-associated hospitalization in infants eligible for RSV immunoprophylaxis during the 2024–2025 season in Italy	Italy	Design: Retrospective cohort study Study period: 2024–2025 season	A total of 362 infants presenting with acute bronchiolitis hospitalization cases were included in this study; 283 of which were RSV and 79 were non-RSV	Posterior probabilities were visualised as log-risk ratios	• Monoclonal antibody BEY FORTUS™ (nirsevimab) by Sanofi
Surie, 2025 (18)	• Effectiveness of 1 dose of respiratory syncytial virus (RSV) vaccine against RSV-associated hospitalization among adults aged 60 years or older during 2 RSV	United States	Design: Multicenter, test-negative, case-control study Study Period: RSV season 1: October 1, 2023 – March 31,	Adults aged 60 years and above hospitalized with acute respiratory illness. They underwent respiratory testing within 10 days of illness onset and 3 days after hospital admission	Vaccine effectiveness was estimated using a test-negative case-control design. Odds ratios (ORs) for prior RSV vaccination among RSV-positive hospitalized cases versus RSV-negative controls were calculated using multivariable logistic regression.	• Bivalent protein subunit (RSV-A and B), mRESVIA (Moderna) mRNA vaccine

Reference (author year) with URL	Research question addressed	Geographical location	Design and Study Period	Population	Analysis	Type of immunization product
	seasons and by time since vaccination		2024 RSV season 2: October 1, 2024 – April 30, 2025		VE was computed as (1 − adjusted OR) × 100%.	• RSVpreF (Abrysvo®, Pfizer)
Lenglart, 2025 (66)	• Effectiveness of nirsevimab treatment in preventing RSV bronchiolitis in pediatric emergency departments during the first and second seasons of implementation of treatment in France	France	Design: Multicenter, test-negative, case-control study Study Period: RSV Season 1: October 5, 2023, to February 29, 2024 RSV Season 2: October 15, 2024, to January 31, 2025	The study included infants younger than 6 months of age who were hospitalized for bronchiolitis during the RSV season	Vaccine effectiveness was estimated using a test-negative case-control design. Odds ratios (ORs) for maternal RSV vaccination among RSV-positive hospitalized infants versus RSV-negative controls were calculated using multivariable logistic regression. VE was computed as (1 − adjusted OR) × 100%.	• RSVpreF (Abrysvo®, Pfizer)
Fry, 2025 (67)	• Effectiveness of RSV protein subunit vaccines in preventing RSV-associated medically attended ARI, emergency department (ED)/urgent care visits, and hospitalizations among adults aged ≥60 years	United States	Study Design: Retrospective test-negative case-control study Study Period: October 1, 2023 – April 30, 2024 (2023–2024 RSV season)	The study population included adults aged ≥60 years with medically attended acute respiratory infection (ARI) who underwent RSV testing during the 2023–2024 RSV season. Cases were defined as individuals who tested positive for RSV, and controls were those who tested negative (excluding those with a prior positive RSV test during the study period). Patients were considered vaccinated if they had documentation of receiving an RSV protein subunit vaccine ≥14 days before RSV testing. For safety analyses, all adults ≥60 years who received an RSV vaccine during the safety study period were included, and incident diagnoses of Guillain-Barré syndrome (GBS) and immune thrombocytopenic purpura (ITP) were assessed.	Vaccine effectiveness was estimated using a test-negative case-control design. Odds ratios (ORs) for prior RSV vaccination among RSV-positive cases versus RSV-negative controls were calculated. VE was computed as (1 − OR) × 100%. Unadjusted ORs were supplemented with stratified analyses by age group (60–74 years vs ≥75 years), immunocompromised status, month of RSV testing, and state of residence to evaluate potential confounding	• Two recombinant RSV prefusion F protein subunit vaccines: RSVPreF3+AS01 & RSVPreF
Payne, 2025 (68)	• Effectiveness of nirsevimab in preventing RSV-associated emergency department (ED) encounters and	United States	Study Design: Retrospective test-negative study	The population included infants aged <8 months who were either aged <8 months as of October 1, 2023 (entering their first RSV season) or born during the study period. Infants	Vaccine effectiveness (VE) was calculated using a test-negative design. Odds ratios (ORs) for prior nirsevimab receipt among RSV-positive cases versus RSV-negative	• Nirsevimab

Reference (author year) with URL	Research question addressed	Geographical location	Design and Study Period	Population	Analysis	Type of immunization product
	hospitalizations among infants during their first RSV season in the United States		Study Period: October 8, 2023, through March 31, 2024, representing the 2023–2024 RSV season in the United States	were included if they had an emergency department (ED) encounter or hospitalization with a diagnosis of RSV-like illness (RLI) and were clinically tested for RSV through routine health care at six participating healthcare systems contributing electronic health record (EHR) data	controls were estimated using logistic regression, with adjustment for age, race and ethnicity, sex, calendar day, and geographic region. VE was computed as (1 − adjusted OR) × 100%.	
Williams, 2025 (69)	• Effectiveness of nirsevimab in preventing RSV-associated hospitalization among infants during their first RSV season in England, following implementation of a national immunisation programme	England (United Kingdom)	Study Design: Multicentre test-negative, case-control study Study Period: Sept 30, 2024, to Jan 20, 2025	The population included infants younger than 1 year of age admitted to hospital with symptoms during the RSV season. Infants were eligible if they were hospitalized and underwent RSV testing as part of routine clinical care. Cases were infants with a positive RSV result, and controls were infants who tested negative for RSV but were admitted with similar respiratory symptoms	Vaccine effectiveness was estimated using a test-negative case–control design. Odds ratios (ORs) for prior nirsevimab receipt among RSV-positive hospitalized cases versus RSV-negative hospitalized controls were calculated using multivariable logistic regression. VE was computed as (1 − adjusted OR) × 100%	• Nirsevimab
Perramon-Malavez, 2025 (70)	• Effectiveness of nirsevimab in hospital-related outcomes (hospitalization, ED visit, PICU admission) of the seasonal cohort and compared them with the catch-up cohort	Spain (Catalonia)	Study design: Retrospective cohort study Study Period: NA	A total of 15,341 infants born between October 1, 2023 and January 21, 2024 were included in the study	Hazard ratios (HRs) for RSV-related outcomes among infants who received nirsevimab versus those not immunized were estimated using Cox proportional hazards regression models with calendar time as the time scale, adjusted for confounders identified via standardized mean differences. Vaccine effectiveness (VE) was computed as (1 − adjusted HR) × 100%	• Nirsevimab
Guerrero-Del-Cueto, 2025 (71)	• Effectiveness of nirsevimab immunization in reducing the risk of hospitalization due to RSV bronchiolitis during the first season of its implementation	Malaga Regional University Hospital, Andalusia, Spain	Study Design: Retrospective, single-center, matched case-control design Study Period: October 1, 2023 to March 31, 2024	The population included infants younger than 24 months hospitalized for PCR-confirmed RSV bronchiolitis during the first nirsevimab season.	Effectiveness of nirsevimab was estimated using a matched case-control design. Logistic regression models estimated odds ratios comparing immunization status between cases and controls; immunization effectiveness was computed as (1 − OR) × 100% with 95% confidence intervals	• Nirsevimab
Gentile, 2025 (72)	• Effectiveness of maternal immunization with RSVpreF vaccine reduced	Argentina	Study Design: Multicentre, case-	Infants under 6 months of age born after 15 March 2024 who were hospitalized for acute lower respiratory	Vaccine effectiveness (VE) was estimated using a test-negative design with logistic regression. The	• RSVpreF (Abrysvo®, Pfizer)

Reference (author year) with URL	Research question addressed	Geographical location	Design and Study Period	Population	Analysis	Type of immunization product
	the risk of RSV-associated acute lower respiratory infections (ALRI) hospitalization in infants under 6 months of age during their first RSV season compared with infants born to unvaccinated mothers		control, test-negative study Study Period: 15 March 2024 and 31 October 2024	infections (ALRI) at one of four pediatric referral hospitals in Argentina were included.	odds of maternal RSV vaccination among RSV-positive cases were compared with RSV-negative controls. VE was calculated as (1 − adjusted odds ratio [aOR]) × 100% with 95% confidence intervals	
Bajema, 2025 (73)	• Effectiveness of RSVPreF3 or RSVpreF vaccination in preventing: 1) Laboratory-confirmed RSV infection, 2) RSV-associated emergency department or urgent care encounters, 3) RSV-associated hospitalization, 4) Severe outcomes (ICU admission and death) among adults aged ≥60 years	United States	Study Design: Retrospective observational study Study Period: Enrollment occurred from September 1, 2023 through December 31, 2023. Follow-up continued through March 31, 2024 (end of the 2023–24 respiratory illness season)	The study included veterans aged ≥60 years receiving care within the U.S. Veterans Health Administration. Veterans were eligible if they were engaged in care (≥1 primary care visit within 18 months prior to each trial month), had no prior RSV vaccination before the trial month, and had no documented RSV infection in the preceding 90 days. RSV infection was identified through routine nucleic acid amplification testing (RT-PCR) of respiratory specimens performed in VHA clinical settings. Vaccination status (RSVPreF3 or RSVpreF) was determined through the VHA electronic health record, including vaccines administered within VHA facilities or documented from outside facilities	The investigators emulated a randomized target trial using four monthly nested sequential trials. Vaccinated individuals were exact-matched on age group, immunocompromised status, frailty (CAN score), region, and prior healthcare utilization, followed by 1:4 propensity score matching. Incidence rates were calculated per 1000 person-years. Cumulative incidence was estimated using the Aalen–Johansen estimator accounting for death as a competing risk. Vaccine effectiveness (VE) was estimated as: VE = 100 × (1 − risk ratio) where the risk ratio compared cumulative incidence between vaccinated and unvaccinated groups at the end of follow-up	• Arexvy (RSVPreF3; AS01E-adjuvanted recombinant stabilised prefusion F protein vaccine) & Abrysvo (recombinant stabilised prefusion F protein vaccine)
Wadia, 2025 (74)	• Effectiveness of nirsevimab in preventing laboratory-confirmed RSV-associated acute respiratory infection (ARI) hospitalization among eligible young children in Western Australia during a single RSV epidemic season	Australia (Western Australia; Perth metropolitan region)	Study Design: Multicentre, case-control, test-negative study Study Period: 1 April 2024 to 30 October 2024	The study included nirsevimab-eligible children hospitalised with acute respiratory infection (ARI) at three hospitals in Perth, Western Australia (Perth Children's Hospital, Fiona Stanley Hospital, and Joondalup Health Campus). Eligible children were identified between 1 April and 30 October 2024 through screening of hospital admission and laboratory	Vaccine effectiveness (VE) was estimated using a test-negative design. Conditional logistic regression models were used to compare the odds of prior nirsevimab receipt among RSV-positive cases versus RSV-negative controls. Effectiveness was calculated as: VE = (1 − adjusted odds ratio) × 100% Models were adjusted for age group, sex, Aboriginal status, prematurity (<37	• Nirsevimab (Beyfortus, Sanofi-Aventis Australia)

Reference (author year) with URL	Research question addressed	Geographical location	Design and Study Period	Population	Analysis	Type of immunization product
				records for ARI symptoms and respiratory viral testing at admission. Cases were children hospitalised with acute respiratory symptoms (<7 days duration) and laboratory-confirmed RSV infection, determined using validated nucleic acid amplification tests (BioFire® Respiratory 2.1 panel or GeneXpert Xpress CoV-2/Flu/RSV plus). Controls were children hospitalised with ARI symptoms who tested negative for RSV. Only children meeting Western Australia's state-based nirsevimab eligibility criteria (first-season infants, newborn cohort, catch-up cohort, and selected high-risk or Aboriginal children entering their second RSV season) were included.	weeks), presence of at least one medical risk factor, and grouped by epidemiologic week and hospital site. Model selection was informed using the Akaike Information Criterion (AIC).	
Marouk, 2025 (75)	• Effectiveness of nirsevimab immunization reduces the risk of hospitalization among infants younger than 3 months presenting to pediatric emergency departments with bronchiolitis during the RSV epidemic season	France (Greater Paris region)	Study Design: Multicentre, observational cohort study Study Period: 2 October 2023 – 31 December 2023	The study population included neonates and infants aged less than 3 months presenting to pediatric emergency departments with a clinical diagnosis of bronchiolitis during the 2023–2024 RSV epidemic season. Participants were identified through the OSCOUR® national emergency department surveillance system, which collects diagnostic coding data from hospitals across France.	The association between nirsevimab immunization and clinical outcomes was evaluated using multivariable logistic regression models. Adjusted odds ratios (ORs) for hospitalization and secondary outcomes were estimated comparing infants who received nirsevimab with those who did not. Vaccine effectiveness was calculated as (1 − adjusted OR) × 100%.	• Monoclonal antibody BEY FORTUS™ (nirsevimab) by Sanofi
Hammitt, 2025 (76)	• Effectiveness of nirsevimab in preventing RSV-associated hospitalization among AI/AN children entering their first or second RSV season in AI/AN communities in the Southwest US and Alaska	United States, specifically AI/AN communities in Alaska and the Southwest United States (Navajo Nation, White	Study Design: Observational test-negative case-control study Study Period: 6 November 6, 2023 and 31 May 2024	The study population included American Indian and Alaska Native children younger than 19 months of age who were hospitalized with acute respiratory illness (LRTI) and were enrolled in an active facility-based surveillance system. Eligible children were screened for LRTI symptoms at	Vaccine effectiveness (VE) was calculated as (1 − adjusted OR) × 100%. Separate models were developed for children entering their first RSV season (<8 months of age) and those entering their second RSV season (8–<19 months). Multivariable models adjusted for potential confounders identified in bivariable	• Monoclonal antibody BEY FORTUS™ (nirsevimab) by Sanofi

Reference (author year) with URL	Research question addressed	Geographical location	Design and Study Period	Population	Analysis	Type of immunization product
		Mountain Apache Tribal lands, Anchorage municipality, and Yukon-Kuskokwim Delta)		participating hospitals. Inclusion required symptoms consistent with LRTI, such as cough, shortness of breath, difficulty breathing, apnea (in infants <6 months), or combinations of systemic symptoms including fever, chills, myalgia, sore throat, vomiting, fatigue, or congestion	analyses, including month of presentation, geographic region (Alaska vs Southwest), and presence of high-risk medical conditions.	
Manzoni, 2025 (77)	• Effectiveness of universal nirsevimab administration in preventing hospitalizations due to RSV-associated lower respiratory tract disease among young infants during the 2024–2025 RSV season in Italy	Italy	Study Design: Multicentre test-negative case-control study Study Period: 1 November 2024 and 30 April 2025	The study population consisted of infants aged 7 months or younger who were hospitalized with lower respiratory tract disease (LRTD) during the RSV season	Immunization effectiveness (IE) was estimated using a test-negative case-control design. The odds of prior nirsevimab immunization among RSV-positive cases were compared with the odds of immunization among RSV-negative controls. Crude odds ratios (cORs) were initially calculated to estimate the association between immunization status and RSV hospitalization Immunization effectiveness was calculated using the formula IE = 100 × (1 − OR), where OR refers to either the crude or adjusted odds ratio derived from the regression models.	• Monoclonal antibody BEY FORTUS™ (nirsevimab) by Sanofi
Attaianese, 2025 (78)	• Effectiveness of a targeted seasonal nirsevimab immunization strategy in preventing RSV-associated hospitalizations among infants younger than 12 months of age in Tuscany, Italy during the 2024-2025 RSV season	Italy (Tuscany region)	Study Design: Observational, multicenter matched case-control study Study Period: 1 November 2024 and 31 March 2025	The study population included infants younger than 12 months of age who were hospitalized during the RSV season at participating pediatric hospitals in Tuscany, Italy. Case patients were infants hospitalized with RSV-associated bronchiolitis confirmed by polymerase chain reaction (PCR) testing of respiratory samples. Control patients were infants hospitalized for non-respiratory conditions (e.g., urinary tract infections, gastroenteritis, feeding difficulties, surgical conditions, jaundice, or poor weight gain) and	Immunization effectiveness was estimated using a matched case–control design. Case patients hospitalized with PCR-confirmed RSV bronchiolitis were matched with control patients hospitalized for non-respiratory conditions based on age and date of hospitalization. Conditional logistic regression models were used to estimate odds ratios (ORs) for prior nirsevimab receipt among cases versus controls while accounting for the matched study design. Multivariable models were further adjusted for sex assigned at birth, gestational age, birth weight, and predefined clinical risk factors for	• Monoclonal antibody BEY FORTUS™ (nirsevimab) by Sanofi

Reference (author year) with URL	Research question addressed	Geographical location	Design and Study Period	Population	Analysis	Type of immunization product
				without respiratory symptoms. Cases and controls were matched in a 1:2 ratio by age (±1 month) and date of hospitalization (±2 weeks). Infants were excluded if parents declined participation, if they had received palivizumab prophylaxis, or if their mothers had received maternal RSV vaccination during pregnancy.	severe bronchiolitis. Immunization effectiveness (IE) was calculated as IE = 100 × (1 − OR).	
Coma 2025 (79)	• Effectiveness of nirsevimab immunisation in preventing RSV-related infections and healthcare utilisation outcomes among infants in the catch-up cohort of the 2024–2025 immunisation campaign in Catalonia	Catalonia, Spain	Study Design: Observational, cohort study (Letter to Editor) Study Period: 1 October 2024 to 16 February 2025	The study included all infants born between April and September 2024 in Catalonia, representing the catch-up cohort of the regional nirsevimab immunisation campaign. Infants were classified into two groups according to nirsevimab immunisation status: those who received nirsevimab and those who did not. Outcomes were identified using health system records from primary care, emergency departments, and hospital admissions. RSV infections were identified through confirmed RSV diagnoses recorded in primary care, and RSV bronchiolitis outcomes were identified through clinical diagnoses of bronchiolitis attributed to RSV within healthcare records, including emergency department visits and hospitalizations.	Effectiveness was estimated using a population cohort design comparing immunised and non-immunised infants. Cox proportional hazards regression models using calendar time as the time scale were fitted to estimate hazard ratios (HRs) and 95% confidence intervals for RSV-related outcomes according to nirsevimab immunisation status. Models were adjusted for covariates with a standardised mean difference greater than 0.1, including nationality and month of birth. Immunisation effectiveness was calculated as (1 − adjusted HR) × 100%. Because the number of paediatric intensive care unit admissions was very low (two events in the control group), effectiveness estimates for this outcome could not be calculated.	• Monoclonal antibody BEY FORTUS™ (nirsevimab) by Sanofi
Reina 2025	• Effectiveness of nirsevimab vaccine against acute respiratory infections diagnosed in the 2022-2023 and 2023-2024 season	Balearic Islands	Design: Comparative analysis Study period: 2022-2023 vs 2023-2024 seasons	A total of 581 youth under the age of 15 were compared; 303 in 2022-2023 and 278 in 2023-2024	Incidences were compared across seasons; analysis not specified	• Monoclonal antibody BEY FORTUS™ (nirsevimab) by Sanofi
Alejandre 2024 (80)	• Evaluate the impact of Nirsevimab immunization	Spain	Design:	This study included 1531 children with severe bronchitis	Differences between groups were explored using a Mann-Whitney U-test	• Monoclonal antibody BEY

Reference (author year) with URL	Research question addressed	Geographical location	Design and Study Period	Population	Analysis	Type of immunization product
	on pediatric intensive care unit admissions		Prospective, descriptive, and observational study Study period: September 2010 and February 2024			FORTUS™ (nirsevimab) by Sanofi
Lassen 2025 (81)	• Effectiveness of RSVpreF vaccine on cardiorespiratory and cardiovascular hospitalizations in older adults aged 60 or older	Denmark	Design: Pragmatic, open-label, individually randomized clinical trial Study period: 2024-2025 northern hemisphere winter season	This study included 131276 older adults aged 60 or older who were randomized to receive the RSVpreF vaccine or a saline placebo	Vaccine effectiveness was calculated using 1 − incidence rate ratio, with 95% confidence intervals	• ABRYSVO™ (RSVpreF) by Pfizer
Pareek, 2025 (82)	• Effectiveness of RSVpreF vaccine in reducing the incidence of RSV-related respiratory tract hospitalizations and major adverse cardiovascular events compared with no vaccination in adults aged ≥ 60 years, and whether vaccine effectiveness differs between those with versus without pre-existing ASCVD	Denmark	Design: Pragmatic, open-label, parallel-group, individually randomized clinical trial Study Period: The trial was conducted during the 2024–2025 Northern Hemisphere winter season, with recruitment in November and December 2024 and follow-up through 31 May 2025	The population comprised older adults aged ≥ 60 years from the general Danish population who were invited to participate via a government digital mail system. Participants were randomized to either receive the RSVpreF vaccine or no vaccine. Baseline and clinical outcome data were obtained through linkage to nationwide administrative and health registries, including diagnostic codes and hospitalization records. Around 10.8 % had pre-existing atherosclerotic cardiovascular disease (ASCVD)	Analyses followed the intention-to-treat principle. Vaccine effectiveness was calculated as: VE = [1 − (incidence rate in vaccine group ÷ incidence rate in control group)] × 100%, with 95% CIs using the Clopper–Pearson method. Outcome incidence rates and VE were summarized by ASCVD status and treatment arm	• Bivalent respiratory syncytial virus prefusion F protein–based vaccine (RSVpreF)
Jabagi 2025 (83)	• Effectiveness of nirsevimab on RSV-LRTI–related hospitalization, RSV-LRTI necessitating admission to a pediatric intensive care unit (PICU) or high dependency unit	France	Design: Population-based cohort study Study Period: 15 September 2023 to 31 January 2024	82,474 infants (41,237 each in immunized and unimmunized group) age 0 to 12 months old were included in the analysis	Vaccine effectiveness was calculated using the Cox proportional hazard ratio: (1 – hazard ratio) x 100	• Monoclonal antibody BEYFORTUS ™ (nirsevimab) by Sanofi

Reference (author year) with URL	Research question addressed	Geographical location	Design and Study Period	Population	Analysis	Type of immunization product
	(HDU), and RSV-LRTI requiring ventilation support or oxygen therapy in infants					
Jeziorski 2025 (84)	• Effectiveness of children hospitalized for all-cause bronchitolotis according to RSV and nirsevimab status for infants 12 months and younger	France	Design: Multicentre prospective study with test-negative design post-hoc analysis Study Period: October 27, 2023 to February 29, 2024	1,015 infants 12 months old or younger were included in the RSV analysis (724 cases and 291 controls). 230 (22.7%) had received nirsevimab including 102 (14.1%) cases and 128 controls (44.9%)	Vaccine effectiveness was estimated using the following equation: effectiveness = 100% x (1 – OR). Odds of RSV infection was estimated using a multivariable logistic regression model	• Monoclonal antibody BEYFORTUS ™ (nirsevimab) by Sanofi
Núñez 2025 (85)	• Effectiveness of nirsevimab in preventing hospital admission due to RSV infection	Spain	Design: Population-based matched case-control study Study Period: September 25, 2023 to March 31, 2024	4,757 infants born after April 1, 2023 were included; this included 2,029 in the catch-up immunisation cohort (406 cases and 1,623 controls) and 2,728 in the at-birth immunisation cohort (546 cases and 2,182 controls)	Pragmatic nirsevimab effectiveness was estimated from conditional logistic regression models adjusted for sex, gestational age, birth weight, multiple pregnancy, previous non-RSV related hospitalization, and previous comorbidities. Intention to treat (ITT) and per protocol (PP) causal estimates used inverse-probability-of-censoring weighted conditional logistic models based on assigned immunisation among uncensored clones at the end of the intervention period and up to the matching date, respectively	• Monoclonal antibody BEYFORTUS ™ (nirsevimab) by Sanofi
Mallah 2025 (86)	• Effectiveness of nirsevimab in preventing RSV-related hospitalizations among infants 0-24 months old within Galicia, Spain	Galicia, Spain	Design: Population-based longitudinal study Study Period: September 25, 2023 to April 15, 2024	Effectiveness outcomes included only data from the catch-up cohort of 7,E62 infants age 0 to 24 months old born between April 1 to September 24, 2023	Vaccine effectiveness was estimated with Cox proportional hazard regression models adjusted for sex and health district area	• Monoclonal antibody BEYFORTUS ™ (nirsevimab) by Sanofi
Lenglart 2025 (87)	• Effectiveness of nirsevimab on ED attendance for RSV-positive bronchiolitis in all	France	Design: Test-negative study	383 infants younger than one year were included; 274 were RSV-positive	A multivariate logistic regression model adjusted for sex, age, underlying chronic disease, prematurity, type of childcare, month and centre of inclusion was used.	• Monoclonal antibody BEYFORTUS ™

Reference (author year) with URL	Research question addressed	Geographical location	Design and Study Period	Population	Analysis	Type of immunization product
	infants younger than 1 across France		Study Period: October 1, 2023 to February 29, 2024		Vaccine effectiveness was calculated as 100 x (1 – adjusted odds ratio)	(nirsevimab) by Sanofi

Table 2: Characteristics of all included studies reporting on the efficacy of RSV immunization products

Reference (author year) with URL	Research question addressed	Geographical location	Design and Study Period	Population	Analysis	Type of immunization product
Curran 2024	• Vaccine efficacy (VE) against medically attended acute respiratory infection and lower respiratory tract disease (LRTD)	Not reported	Design: Observer blind multi-country randomized trial Study period: N/A	24,960 adults (over the age of 60) were included	VE was estimated using the conditional exact binomial method based on the Poisson model	• AREXVY™ (RSVPreF3 OA)
Walsh 2023	• VE against RSV-associated lower respiratory tract illness (LRTI) based on signs and symptoms and overall among older adults (60 years and older)	**Multinational (**Argentina, Canada, Finland, Japan, the Netherlands, South Africa, United States)	Design: Phase three, multinational, double-blinded, randomized, placebo-controlled trial Study period: 31 August 2021–14 July 2022	34,284 participants (aged ≥60 years) received one intramuscular 120-ug dose of RSVpreF or placebo	Used a risk ratio-based approach to calculate VE, comparing the incidence of RSV-associated LRTI and acute respiratory illness between the vaccine and placebo groups, with confidence intervals calculated using a conditional exact test adjusted for interim analysis using Pocock error spending	• RSVpreF
Kampmann 2023	• VE against RSV-associated both severe LRTI, hospitalization, and all-cause LRTI	18 countries (Argentina, Australia, Brazil, Canada, Chile, Denmark, Finland, Gambia, Japan, Mexico, the Netherlands, New Zealand, Philippines, Republic of Korea, South Africa, Spain, Taiwan, United States)	Design: Phase three, multinational, randomized, placebo-controlled trial Study period: 17 June 2020–24 November 2023	7,358 women were randomly assigned one dose of 120 ug of RSVPreF vaccine or placebo; 3,570 infants (0 to 2 years old) whose mothers received RSVpreF and 3,558 infants whose mothers received placebo were included The two endpoints were either medically attended severe RSV-associated LRTI and medically attended RSV-associated LRTI in infants at 90, 120, 150, and 180 days after birth	Binominal distribution of the number of cases of disease in the RSV vaccine group and given the total number of cases in both groups	• Maternal RSVpreF
Papi 2023	• VE against RSV-associated LRTD, severe LRTD, and acute respiratory infection (ARI)	Multinational including 17 countries in Africa, Asia, Australia, Europe and North America	Design: Phase three, multinational, randomized, placebo-controlled trial Study period: 25 May 2021–31 January 2022	A total of 24,966 participants (aged ≥60 years)	One minus the relative risk with the use of the conditional exact binomial method based on the Poisson model	• RSVpreF3-OA

Reference (author year) with URL	Research question addressed	Geographical location	Design and Study Period	Population	Analysis	Type of immunization product
Simões 2023	• Efficacy of nirsevimab against RSV-related LRTI and hospital admissions in infants	Multinational • Phase 2b trial: 164 sites across 23 countries in Europe, North America, South America, and Australasia • MELODY primary cohort: 160 sites across 21 countries in Europe, North America, Asia, and South Africa • MEDLEY: 126 sites across 25 countries in Europe, North America, Asia, and South Africa	Design: Double-blind, randomized, controlled trials Study period: 7 July 2019–30 September 2021	2,350 infants: 860 infants born preterm (≥29 to <35 weeks gestational age) who weighed less than 5 kg in the phase 2b trial, and 1,490 infants born at term or late preterm (≥35 weeks' gestational age) in the primary cohort of the MELODY trial	Intention-to-treat population using Poisson regression model with robust variance adjusted for age and location and multiple imputation; a prespecified subgroup analysis assessed data by hemisphere, age at randomization, sex, ancestry or ethnic group, weight at baseline, country, and geographical region Post hoc exploratory endpoints of health resource use, outpatient visits, and antibiotic use were also assessed	• Monoclonal antibody (nirsevimab)
Drysdale 2023	• Efficacy of nirsevimab compared to standard care, on hospitalization, ICU admission, and LRTI	France, Germany, United Kingdom	Design: Phase 3b, open-label, two-group, randomized trial Study period: 8 August 2022–28 February 2023	A total of 8,058 infants (12 months or younger) participated in this study (4,037 vaccinated, 4,021 standard care)	A time-to-first event analysis and Cox proportional-hazard regression model was used adjusted for age group and country; P values and Bonferroni corrections were calculated for primary and secondary endpoints	• Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi
Ison 2024	• VE over two seasons of one dose of RSVPreF3 OA or two doses administered in consecutive RSV seasons in adults aged ≥60 years against RSV-associated LRTD, medically attended RSV-LRTD, severe RSV-LRTD, and acute respiratory infection	Belgium, Canada, Estonia, Finland, Germany, Italy, Japan, Mexico, Poland, South Korea, Russian Federation, Spain, United Kingdom, United States, Australia, New Zealand, South Africa	Design: Randomized, placebo-controlled trial Study period: 25 May 2021–31 January 2022	24,973 participants (aged ≥60 years), in season one 12,470 received RSVPreF3 OA and 12,503 received placebo In season two 19,990 of the original participants were included; 4,966 were revaccinated, 4,991 received a placebo as their second dose (but had previously received the first vaccine dose), and 10,033 received their second placebo dose	This study uses the conditional exact binomial method based on a Poisson model to estimate over the course of two seasons the efficacy of one RSVPreF3 OA dose followed by revaccination a year later against RSV-associated LRTD, severe RSV-LRTD, and RSV-associated ARI in adults ≥60 years old Season, age, and region were covariates in the model Secondary analyses were performed for efficacy based on RSV subtype,	• RSVPreF3 OA

Reference (author year) with URL	Research question addressed	Geographical location	Design and Study Period	Population	Analysis	Type of immunization product
					season, year, age, comorbidities, and frailty	
Griffin 2020	• Evaluation of nirsevimab efficacy against medically attended RSV-associated LRTI and hospitalization due to RSV-LRTI	Argentina, Australia, Belgium, Brazil, Bulgaria, Canada, Chile, Czech Republic, Estonia, Finland, France, Hungary, Italy, Latvia, Lithuania, New Zealand, Poland, South Africa, Spain, Sweden, Turkey, United Kingdom, United States	Design: Randomized, placebo-controlled trail Study period: 3 November 2016–1 December 2017	1,453 preterm infants (born at gestational age 29 weeks 0 days to 34 weeks 6 days ≤1 year old) included, 969 (66.7%) received nirsevimab and 484 (33%) received placebo	This study uses a Poisson regression model to evaluate nirsevimab against RSV-associated medically attended LRTI and RSV-associated hospitalization in preterm infants) ≤1 year old A Cochran-Mantel-Haenszel test and Kaplan-Meier curves were used for secondary analyses Subgroup analyses were performed for efficacy based on hemisphere, age, sex, race, gestational age, and siblings (twins/triplets)	• Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi
Otsuki 2024	• VE of maternal RSVpreF against medically attended RSV-LRTI (RSV-MA-LRTI), severe RSV-MA-LRTI, RSV-associated hospitalization, and all-cause medically attended LRTI (MA-LRTI) in infants	Japan	Design: Randomized controlled trial Study period: 12 November 2020–2 September 2022	462 maternal participants (≤49 years old at 24–36 weeks' gestation) were vaccinated with RSVpreF (230) or placebo (232); 434 infants were followed after birth (218 were born to mothers who received RSVpreF, 216 were born to mothers who received placebo) until 12–24 months old	Calculated using the equation 1-(hP/[1-P])	• ABRYSVO™ (RSVpreF) by Pfizer
Schmoele-Thoma 2022	• VE of RSVpreF against symptomatic RSV infection confirmed by viral detection on two consecutive days, symptomatic RSV infection confirmed by two quantifiable RT-qPCR results on ≥2 consecutive	Not reported	Design: Phase 2a, single-centre, randomized, double-blind, exploratory study Study period: N/A	70 healthy adults (age 18-50 years old) were randomized to receive the RSVpreF vaccine (n = 35) or placebo (n = 35); 62 participants (31 in each group) were challenged with the RSV A Memphis 37b preparation; 60 participants completed the full 12-day observation	VE against RSV infection was estimated using the equation (1 – incidence rate ratio) x 100% using the intention to treat population	• ABRYSVO™ (RSVpreF) by Pfizer

Reference (author year) with URL	Research question addressed	Geographical location	Design and Study Period	Population	Analysis	Type of immunization product
	days, culture-confirmed symptomatic RSV infection, and RSV infection regardless of symptom confirmed with RT-qPCR results on ≥2 consecutive days or a quantifiable culture-confirmed infection					
Walsh 2024	• VE over two seasons of one dose of RSVpreF3 against RSV-associated LRTD in adults aged ≥60 years with at least three symptoms	Argentina, Canada, Finland, Japan, the Netherlands, South Africa, United States	Design: International phase 3, double-blind, randomized, placebo-controlled trial Study Period: 12 July 2022–6 November 2023	18,050 participants (aged ≥60 years) were at risk in the RSVpreF group at the end of season 1; 16,164 participants were at risk in the RSVpreF group at the end of season 2; across both seasons, 18,050 participants in the RSVpreF group were at risk at some point 18,074 participants (aged ≥60 years) were at risk in the placebo group at the end of season 1; 16,059 participants in the placebo group remained at risk at the end of season 2; across both seasons, 18,074 participants in the placebo group were at risk at some point	VE was calculated using case count ratio, calculated as 1 – (P/[1–P]), where P is the number of RSVpreF cases divided by the total number of cases; cases in season 1 and season 2 were pooled to estimate the VE across both seasons	• ABRYSVO™ (RSVpreF) by Pfizer
Wilson 2023	• VE against RSV-associated LRTD (with at least two signs or symptoms and with at least three signs or symptoms) and RSV-associated acute respiratory disease	Multiple – 22 countries (not reported in detail)	Design: Randomized, double-blind, placebo-controlled study Study period: 17 November 2021–31 October 2022	35,541 participants were randomized, where 17,793 participants were assigned to the mRNA-1345 group and 17,748 were assigned to the placebo group. The mean age of the participants at enrollment was 68.1 years, 49.0% were women, 36.1% were non-White, and 34.5% were Hispanic or Latino	Vaccine efficacy was calculated as 1 – hazard ratio (mRNA – 1,345 vs. placebo) x 100% The confidence interval for VE was based on a stratified Cox proportional-hazards models in the per-protocol efficacy population	• mRNA-based RSV PreF (mRNA-1345)

Reference (author year) with URL	Research question addressed	Geographical location	Design and Study Period	Population	Analysis	Type of immunization product
				One or more coexisting conditions were reported by 29.3% of the participants, with 1.1% reporting a history of congestive heart failure and 5.5% reporting a history of chronic obstructive pulmonary disease (COPD) A total of 21.9% of the participants were assessed as vulnerable or frail, as defined according to the Edmonton Frailty score All participants who had undergone randomization completed at least one visit or surveillance contact 14 days after injection		
Zar 2025	• Efficacy of Clesrovimab vaccine against RSV-associated medically attended lower respiratory infection after 150 days of injection in infants under the age of one	Argentina, Belgium, Canada, Chile, China, Colombia, Denmark, Finland, France, Italy, Japan, Korea, Malaysia, Mexico, Peru, Philippines, Poland, South Africa, Thailand, Turkiye, United Kingdom, United States	Design: Double-blind, randomized, placebo-controlled trial Study period: 5-6 month period not stated	A total of 3614 infants under the age of one were included in this study; 2412 in the Clesrovimab group and 1202 in the placebo group	**Vaccine efficacy was calculated using Poisson regression with robust variance** Efficacy was calculated as 1 minus the relative risk (as estimated with the Poisson model) Incidence rates were calculated as the number of cases during the follow-up period divided by the total follow-up time, multiplied by the month rate	• Clesrovimab
Muller 2023	• Describe the efficacy of the Nirsevimab vaccine for the prevention of RSV in infants	Commentary based in USA	Design: Commentary Study period: Not stated	This commentary focused on infants who were term or late term	NA	• Monoclonal antibody BE YFORTUS™ (nirsevimab) by Sanofi

Reference (author year) with URL	Research question addressed	Geographical location	Design and Study Period	Population	Analysis	Type of immunization product
Feldman 2024	• Evaluate vaccine efficacy and immunogenicity of a single dose of RSVPreF3 OA in adults aged ≥60 years with coexisting cardiorespiratory and endocrine or metabolic conditions associated with an increased risk of severe RSV disease	17 countries in Africa, Asia, Australia, Europe, and North America	Design: Phase 3, randomized, placebo-controlled trial Study period: 1 October 2021 to 30 April 2022 (Northern hemisphere); 1 March 2022 to 30 September 2022 (Southern hemisphere)	26 664 adults aged ≥60 years old were enrolled in the trial, of whom 24 966 were part of the exposed population (12 467 received RSVPreF3 OA and 12 499 received placebo)	Vaccine efficacy for first occurrence of RSV-ARI and RSV-LRTD was calculated as 1 minus the relative risk with the conditional exact binomial method based on a Poisson model.	• ABRYSVO™ (RSVpreF) by Pfizer
Ison 2025	• Efficacy if RSVPreF3 OA) against lower respiratory tract infection in persons older than 60	Africa, Asia, Oceania, Europe, and North America (specific countries unstated)	Design: Randomised, observer-blind, placebo-controlled, phase 3 trial Study period: May 25, 2021, and Jan 31, 2022	This study included participants 60 years across 275 centres in 17 countries	Cumulative efficacy was analyzed in RSV-related acute respiratory illness within 15 days post-dose one Efficacy was defined as 1 – the incidence rate ratio	• ABRYSVO™ (RSVpreF) by Pfizer
Simoes 2025	• Efficacy of RSVpreF on LRTD and hospitalization outcomes within 180 days of birth infants born to healthy pregnant participants aged 49 years or younger, within the 24-36 week gestation period	United States	Design: Phase 3, randomized, double-blinded, placebo-controlled trial Study period: June 17, 2020, to October 27, 202	This study focused on 7420 healthy pregnant participants aged 49 years or younger, within the 24-36 week gestation period. Of these women, 7307 children were born and were explored for efficacy analysis	Vaccine efficacy was analyzed using relative risk ratio	• RSVpreF

Reference (author year) with URL	Research question addressed	Geographical location	Design and Study Period	Population	Analysis	Type of immunization product
Munro 2025	• Efficacy of a single dose of nirsevimab provide sustained protection (up to 180 days) against hospitalization in infants during their first RSV season?	France, Germany, United Kingdom	Study Design: Multicentre, open-label, parallel-group, randomized controlled phase 3b trial (HARMONIE trial - NCT05437510) Study Period: August 8, 2022 – February 28, 2023 (Enrolment)	Eligible participants were otherwise healthy infants aged 12 months or younger who were entering their first RSV season and were born at a gestational age of at least 29 weeks. Infants could be enrolled either before or during the RSV season in their respective country. Participants were required to be ineligible for palivizumab prophylaxis and have parental or legal guardian consent. Key exclusion criteria included prior receipt of RSV prophylaxis or conditions that would make participation unsafe according to investigator assessment.	Efficacy was assessed in the intention-to-treat population. Incidence rates of RSV-associated hospitalization were calculated per person-month of follow-up. Nirsevimab efficacy was defined as (1 − incidence rate ratio) × 100%, using exact binomial methods accounting for follow-up time.	• Nirsevimab
Arbetter 2025	• Efficacy of nirsevimab on LRTI in infants	United States	Design: Randomized clinical trial Study period: 23 July 2019 and 22 October 2021	A total of 3012 infants were randomized to receive the nirsevimab vaccine (n = 2009) or placebo (n = 1003)	Incidence rates were calculated using a pre-determined formula	• Monoclonal antibody BE YFORTUS™ (nirsevimab) by Sanofi
Walsh 2025	• Vaccine efficacy of RSVpreF against RSV-related LRTI in older adults in multiple countries	Multiple: United States, Canada, Japan, Finland, Netherlands, Argentina, South Africa	Design: Phase 3, randomized double-blind placebo-controlled trial Study period: 31 August 2021 and 18 December 2023	36,862 adults aged ≥60 years (median 67 years; 62.6% aged 60-69, 5.5% ≥80; 51% male, 52.3% with ≥1 prespecified high-risk condition like chronic cardiopulmonary disease), healthy or with stable medical conditions	Poisson regression model for vaccine efficacy hazard ratio with 95% CIs, post hoc Cox proportional hazards model to assess heterogeneity between seasons, enabling pooled VE across two seasons	• ABRYSVO™ (RSVpreF) by Pfizer

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