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RSV vaccines indicators

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Burden & epidemiology

Number of new cases per year (last 3-5 years)

Based on the latest available global modelled estimates for 2019, about 33 million episodes of Respiratory Syncytial Virus (RSV)-induced acute lower respiratory infections (ALRI) occurred in children aged under 5 years of age; one in five episodes occur in children aged 0-6 months.[1]

Proportion of the population affected by the disease or infected with the antigen

By two years of age almost all children will have been infected with RSV, with approximately 25-33% developing ALRI. RSV infections recur throughout life, but disease severity is lower in older children and healthy young adults and begins to rise again among elderly persons (e.g., over 65 years of age).[2, 3]

A systematic review and meta-analysis from low- and middle-income countries (LMICs) estimated that 26.2% of children aged under 5 years hospitalized with ALRI were RSV-positive. This ranged from 18.9% among children 6– < 60 months to 41.3% among children 0– < 6 months.[4]

Another systematic review of the age distribution of RSV disease in children aged under five years in LMICs showed that the mode (peak) age was three weeks for non-facility deaths, four weeks for facility deaths, seven weeks for ICU admissions, 17 weeks for inpatient admissions, 10 weeks for emergency room visits, 28 weeks for outpatient or clinic visits, and 22 weeks for community cases.[5] Over a half of ICU admissions and deaths and over a third of emergency room visits and hospitalizations were in infants aged below six months.

Most pooled LMIC estimates rely on pre-COVID datasets, so post-pandemic seasonality changes are not captured.

Serogroup or serotype distribution (for serogroup- or serotype-specific vaccines)

RSV strains are grouped within a single serotype but are separated into two subgroups: RSV-A and RSV-B and both can cause severe disease. Both subgroups co-circulate during an RSV season; however, the dominating subgroup is unpredictable and varies across annual outbreaks.[6, 7]

Number of deaths from the disease per year

In children aged under 5 years, an estimated 101 400 deaths occurred in 2019; 97% of all deaths were estimated to have occurred in LMICs. Of the total deaths, 45 700 were estimated to have occurred in infants aged below six months [8, 9]

Case Fatality ratio (number of deaths / number of new cases, in %)

The estimated case fatality ratio (CFR) in hospitalized children aged 0 - 60 months is 0.1% in high-income countries (HICs), 0.6%–0.8% in LMICs, and 1.4% in low-income countries (LICs).

Community mortality studies show that a high and unmeasured burden of RSV deaths in children in LMICs occur at home; in these settings, it is estimated that 4 deaths occur in the community for every 1 in-hospital death.[10]

Outbreak, epidemic or pandemic risk

Seasonal epidemics occur every year in the general population in most, but not all, locations globally. Nosocomial outbreaks have been reported in several health care settings, including paediatric and neonatal intensive care units, adult stem cell transplant units, and adult haematology and oncology units in LMICs. RSV outbreaks have also been reported among older adults in long-term care facilities. RSV is not a virus of pandemic potential.[11]

Contribution of the vaccine to achievement of the national, regional or global disease goals

Currently there is no global or regional elimination or control goal for diseases caused by RSV.

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Benefits of the intervention

Serogroup or serotype coverage by vaccines considered (for serogroup- or serotype-specific vaccines)

Currently authorized RSV immunization products protect against both subgroups of RSV.[12, 13, 14]

Efficacy and effectiveness estimates (e.g. against infection, disease, hospitalization, death), including in different populations

Both maternal RSV Pre-F vaccine and the two monoclonal antibody preparations (nirsevimab and clesrovimab) were shown to protect infants against RSV diseases during the first 5-6 months of life.

Maternal vaccination with RSV Pre-F demonstrated efficacy of 70% (95% CI: 50.6- 82.5) against RSV-positive severe medically attended ALRI and 49.2% (95% CI: 31.4, 62.8) against any RSV-positive medically attended LRTI, respectively, up to 180 days after birth.[15]

Similar levels of protection have been observed in post-marketing studies.

In Argentina, maternal vaccination at 32–36 weeks gestation demonstrated vaccine effectiveness (VE) of 71.3% (95% CI: 53.3–82.3) against RSV-associated ALRI hospitalization and 76.9% (95% CI: 45.0–90.3) against severe RSV-associated ALRI hospitalization through six months of age.[16]

In the United Kingdom, during the 2024–2025 RSV season, maternal vaccination from 28 weeks gestation showed VE of 58% (95% CI: 28–75) against infant RSV hospitalization overall and 72% (95% CI: 48–85) when vaccination occurred more than 14 days before delivery.[17] During the 2025-26 season VE of 61% (95% CI: 38-75) against RSV-positive hospital admission in infants aged six months and 76% (95% CI: 54-87) in infants aged <3 months were observed.[18]

In healthy term and late preterm **infants**, the efficacy of the mAb (nirsevimab) was 76.4% (95% CI: 62.3- 85.2) against medically attended RSV-associated ALRI, 76.8% (95% CI: 49.4- 89.4) against hospitalization for RSV-associated ALRI and 78.6% (95% CI: 48.8-91.0) against very severe medically attended RSV-associated ALRI up to 5 months after administration.[19] In preterm infants (29-36 weeks gestational age), the efficacy of a single dose of nirsevimab was 70.1% against medically attended RSV ALRI and 78.4% against hospitalized RSV ALRI.[20]

In a large phase 3b randomized study conducted across several European countries in ~8000 full-term infants and preterm infants (born ≥29 weeks' gestation) entering their first RSV season, nirsevimab reduced hospitalizations due to RSV-associated ALRI by 82.7% (95% CI: 67.8-91.5) over a 180-day follow-up period.[21]

During the first season of use in Chile, combined VE (for seasonal and catch-up cohorts) of nirsevimab was 76.4% (95% CI: 72.5-79.7) against RSV-related ALRI hospitalizations, 84·9% (95% CI: 79.5-89.0) against RSV-related ICU admissions, 66.5% (95% CI: 62.0-70.5) against all-cause ALRI hospitalizations and 47.9% (95% CI: 44.4-51.2) against all-cause hospitalizations.[22]

Administration of nirsevimab was associated with a lower odds of RSV-related hospitalisation (odds ratio 0.17; 95% CI: 0.12–0.23), a lower odds of ICU admission (0.19; 95% CI: 0.12–0.29), and a lower odds of ALRI incidence (0.25; 95% CI: 0.19–0.33) in infants aged 0–12 months in a meta-analysis of the effectiveness of nirsevimab across 27 studies from Spain, France, USA and Luxembourg.[23]

A single injection of 105 mg of clesrovimab showed an efficacy of 60.4% (95% CI: 44.1-71.9) against medically attended ALRI, and efficacy of 84.2% (95% CI: 66.6-92.6) against RSV-associated hospitalization during 150 days of follow up.[24]

In children at high risk for severe RSV disease entering their second RSV season and eligible for palivizumab (short-acting mAb), incidence rates of RSV-associated medically attended lower respiratory infection were comparable between those who received a single dose of 201 mg of clesrovimab and monthly doses of palivizumab (3.2% and 3.4%, respectively) through day 150 in season 1.[25]

A phase 4 clinical trial (RSV_IMPACT study) is ongoing in four African countries to evaluate the safety and impact of RSV Pre-F maternal vaccine in these settings. The duration of follow up is 365 days after birth; the study is expected to be completed in February 2028.[26]

Duration of protection and waning of immunity in general and risk groups

Both the RSV Pre-F maternal vaccine and nirsevimab provide about 5-6 months of protection to infants.

RSV Pre-F provided protection between 5-6 months following maternal vaccination; RSV antibody titres remained high six months after birth.[27, 28]

Similarly, efficacy outcomes measured at five months after nirsevimab, and clesrovimab administration indicated protection up to five months.[29, 30, 31]

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Safety of the intervention

Type, including severity, consequences and frequency of short- and long-term adverse events following vaccination

Following **RSV Pre-F** vaccination during pregnancy, recipients may experience injection site pain, which is mild to moderate. Systemic symptoms, including muscle pain and headaches may also occur.[32]

In clinical trials, serious adverse events included a numerical increase in preterm births in maternal vaccine recipients (this was not statistically significant overall, and available data are insufficient to establish or exclude a causal relationship between preterm birth and the vaccine).[33]

A numerical imbalance in preterm births (< 37 weeks gestation) was observed between the groups, occurring in 5.7% of vaccine recipients and 4.7% of placebo recipients (relative-risk [RR]: 1.20; 95% CI: 0.98–1.46).

When the data were stratified by country income levels, the numerical increase in pre-term births was most notable in the two upper-middle-income countries (UMICs), namely Argentina and South Africa.[34]

The safety of RSV pre-F vaccine, specifically the risk of excess pre-term births is being further evaluated in the ongoing RSV_IMPACT study in sub-Saharan African settings.[26]

Post-authorization safety evaluations in high-income countries and UMICs that have introduced the vaccine have not shown any risk of excess pre-term infants.[35]

Unpublished post-marketing data presented to the Global Advisory Committee on Vaccine Safety (GACVS) in June 2026 did not show any excess pre-term births following maternal Pre-F vaccine use in Australia, Argentina, Brazil and the United Kingdom.[36]

In a modelling study looking at risk-benefit in South Africa, maternal vaccination was estimated to prevent 31 RSV-associated infant deaths per 100 000 live births, but if the increase in preterm births occurred at the same rate observed in the trial, the model predicted that neonatal deaths

related to prematurity could increase by 44 per 100 000 births when vaccination occurred between 24–36 weeks of gestation. However, if vaccination was limited to 27–36 weeks gestation, the predicted risks were substantially lower, and in 97% of simulations the benefits outweighed the risks. Overall, the findings suggest that third-trimester RSV Pre-F vaccination may provide a more favourable benefit-risk balance.[37]

Since the risk of pre-term births was mainly observed at two upper-middle-income country sites and data were very sparse from low- and low-middle-income countries, a trial that is powered to detect the risk of excess pre-term births has been initiated in four sub-Saharan African countries (the IMPACT study).[26]

In postmarketing safety surveillance in Spain, the common adverse events reported following the administration of **nirsevimab** included maculo-papular and papular rash, and injection site pain, induration, oedema and swelling. The rate of serious adverse events was 23.1/ 100 000 doses administered. No antibody-dependent enhancement or other unexpected risks were reported.[38]

In healthy pre-term and term infants, serious adverse events were reported in 278 of 2 409 infants (11.5%) in the **clesrovimab** group and 149 of 1 202 infants (12.4%) in the placebo group.[30] In children at high risk for severe RSV disease entering their second RSV season, a 210 mg dose of clesrovimab was well tolerated.[25]

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Values and preferences

Perception of the target population on the risk of disease

Bronchiolitis, the most common manifestation of RSV ALRI, is recognized by mothers in LMICs when they are shown videos of the condition; prevention of this syndrome is desired by pregnant and lactating persons. However, name recognition of RSV is low in most LMICs.[39]

In the Gambia, where RSV infection is a common cause of respiratory disease in children aged under five years of age, a study found critical knowledge gaps in healthcare workers. Laboratory confirmation was infrequently sought, and masking was rarely observed while providing care to

infected children to limit the spread of infection within the facility.[40]

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Acceptability to stakeholders

Acceptability of the vaccine and of vaccination against the disease

Acceptability of RSV maternal vaccine is dependent on increasing the awareness of RSV.

Stakeholder acceptability will depend on increased awareness of the pathogen, the diseases it causes and the potential benefit of the vaccine against diseases that they recognize. However, the cost of RSV vaccination is likely to influence how national immunization programmes will prioritize its introduction relative to other vaccines and public health interventions.[41]

A systematic review of 61 studies found that knowledge and awareness of RSV prevention are generally low, but attitudes toward vaccines and other preventive options are mostly positive across target populations. Acceptance is driven by perceived disease severity and protection benefits, while safety concerns act as key barriers, with maternal vaccination generally viewed more favourably than infant immunization.[42]

In the Gambia, willingness to receive maternal RSV vaccination during pregnancy or lactation was high despite low awareness of RSV. Safety concerns and limited awareness were the main barriers to vaccine acceptance.[43]

Both maternal and infant RSV immunization strategies were generally seen as acceptable and feasible in Kenya, Nepal, and Peru when integrated into existing health systems. However, successful introduction will depend on country-specific factors such as community acceptance, health system capacity, availability of epidemiological data, and affordability.[44]

For mAbs, acceptability to key stakeholders will depend on whether the price of the product is affordable in the country. Wide use of mAbs for passive immunization has never been implemented in LMICs.[45, 46]

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Financing & funding

Estimated financial cost of materials per vaccine dose (syringes, needles, safety box) (in USD)

Price for one auto-disable (AD) syringe and needle

- As of October 2025, the UNICEF procurement price for 2026 ranges from US$ 0.023 to US$ 0.046, depending on supplier and product.[47]
- The 2026 PAHO Revolving Fund for Access to Vaccines price ranges from US$ 0.03 to US$ 0.04, depending on supplier and product.[48]

Price for one 5-litre safety box

- The UNICEF procurement price for 2026 ranges from US$ 0.375 to US$ 0.860, depending on supplier and product.[49]
- The 2026 PAHO Revolving Fund for Access to Vaccines price ranges from US$ 0.41 to US$ 0.47, depending on supplier and product.[48] Each 5-litre safety box can hold around 100 syringes.

Syringe price per dose is estimated to be equal for both the maternal vaccine and the infant mAb. The safety box price per dose is also estimated to be the same between both products.

For prefilled-syringe mAb presentations, separate needle/syringe procurement depends on presentation; safety box use remains relevant.

Estimated vaccine financial cost per dose (in USD)

The country-reported prices per dose for 2025 for maternal RSV Pre-F vaccine in HIC and UMICs ranged between US$ 49.0 and US$245.9.[50]

The 2025 price reported by the PAHO Revolving Fund for the maternal RSV Pre-F vaccine for participating countries was US$ 49 per dose.[51]

As of June 2026, price per dose for the maternal vaccine in the United States of America ranges between US$ 240 and US$ 319. The price per dose for the monoclonal antibody ranges between US$ 422 and US$ 595.[52]

The Gates Foundation provided Pfizer with a grant to support the development of an affordable multidose vial for delivery of the RSV vaccine candidate in lower-income countries via public sector purchasers, including Gavi. [53]

Gavi and the manufacturer of the RSV Pre-F maternal vaccine are working towards sharing a directional price with countries in 2026, subject to final tendering and contracting through UNICEF. All Partners are working towards introducing the RSV multidose vial affordably and in line with other vaccines made available through the Gavi to eligible countries.

The country-reported price range for nirsevimab in 2025 ranged between US$ 258.8 and US$ 320.4.[50]

To date, no price commitment for LMICs for any mAb has been made.

Estimated financial cost per person vaccinated (in USD)

Globally, the estimated financial cost per person vaccinated varies between countries. In 2018, the reported cost of delivering a maternal vaccine ranged from US$ 0.55 to US$ 0.64 for LICs, US$ 1.25 to US$ 6.55 for MICs, and US$ 5.76 to US$ 39.87 in HICs.[54]

Recent prospective maternal immunization costing studies suggest that the delivery cost (excluding the vaccine price) per dose is similar to that of vaccines for infants and young children, between US$ 0.45 - 1.81 (financial) and US$ 2.01 - 4.49 (economic) in South Asia, and between US$ 1.74 - 3.42 (financial) and US$ 2.21- 6.6 (economic) in sub-Saharan Africa. Key cost drivers include health worker training, social mobilisation, and programme planning.[55], [56], [57]

The UNICEF financial cost estimate for delivering birth dose vaccines (BCG and the HepB vaccines) is US$ 2.34; this provides an estimate of delivery costs for nirsevimab as a birth dose. In addition to these costs, the direct cost of the vaccines and mAb per dose will need to be

included (currently unknown for LMICs).[58]

Cost-effectiveness ratio

A study evaluating RSV intervention cost effectiveness in 133 LMICs found that RSV interventions could be cost saving in one-third of countries evaluated and cost-effective in the remaining countries at willingness-to-pay threshold of 0.5 GDP per capita and when the price for the maternal RSV Pre-F vaccines was US$ 3.50 and the price of the mAb was US$ 3.50 per dose, respectively.[59]

Under the anticipated lower prices for maternal RSV Pre-F vaccine, immunization is expected to be more cost-effective than using nirsevimab.[60]

In a cost-effectiveness analysis in the United States of America, when compared with palivizumab, clesrovimab and nirsevimab were estimated to cost US$ 38 655 and US$ 79 912 per QALY, respectively. Results were sensitive to changes in intervention costs, efficacy, and QALY loss due to RSV infection.[61]

Cost–effectiveness varies considerably by several factors, including, the burden of disease, vaccination coverage, vaccine price, delivery costs, delivery approaches, and schedules. Caution is recommended when comparing estimates of cost-effectiveness for different interventions evaluated by different methods and in different contexts (e.g., with different concurrent health interventions and standards of care).

Is there a Gavi programme to support the introduction of this vaccine? If a Gavi programme is available, what support is available to countries?

Both the maternal vaccines and infant long-acting mAbs were approved in-principle in the 2018 Gavi Vaccine Investment Strategy, subject to specific conditions.[62]

As part of Gavi Strategy 2026-2030 (Gavi 6.0), maternal RSV Pre-F vaccine is supported through the discretionary vaccine budget. All Gavi-eligible countries that have not introduced the maternal RSV vaccination in their national vaccination schedule are eligible for support. A multi-dose vial formulation of the vaccine, now pre-qualified by WHO, will be available via Gavi

support.[63]

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Market (feasibility)

Available vaccines, licensing status, prequalification status, presentation, formulation, dosage and route of administration

There is currently one maternal RSV Pre-F vaccine (Abrysvo®, Pfizer) and two long-action mAbs, nirsevimab (Beyfortus®, Sanofi) and clesrovimab (Enflonsia®, MSD), that have received marketing authorisation.[64] Two additional mAbs received market authorization in China.[65, 66]

Currently only the RSV Pre-F maternal vaccine (Abrysvo®, Pfizer) is WHO prequalified.[67] The multidose vial presentation was also prequalified by WHO, on 24 August 2026.[67]

Detailed information on the different products can be found in the comparison table.[68]

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Service delivery (feasibility)

Number of doses and timing of administrations

Both the maternal RSV Pre-F vaccine and the two available mAb products require only a single dose.

Maternal vaccination with the RSV Pre-F vaccine is recommended by WHO for use in the third trimester of pregnancy.

Nirsevimab is available in two weight-band dosages: 50 mg for infants <5 kg and 100 mg for infants ≥ 5 kg. WHO recommends that it be given to infants at birth or soon after if a year-round strategy is adopted. If a seasonal administration strategy is adopted, a single dose is

recommended for infants aged up to 12 months, beginning shortly before the start of the RSV season, as well as at birth or the earliest opportunity thereafter for infants born during the RSV season.[69, 70]

Clersovimab has one single dosage 105 mg and is recommended to be given to infants at birth or before start of the RSV season.[71] It has been recommended for use for the protection of infants up to 12 months of age in a few countries.[72, 73] As of August 2026, WHO has not yet reviewed the evidence in order to issue formal recommendations on the use of clesrovimab.

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Logistics (feasibility)

Cold chain volume required per vaccine dose (in cm3)

Volume requirements depend on product type and presentation: the maternal RSV Pre-F vaccine require 12.1 cm3/dose, whereas the cold chain volume for mAbs ranges from 53.3 to 134 cm3/dose.[68]

For specific product characteristics see the comparison table.[68]

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