RSV vaccines indicators

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Burden & epidemiology

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

In 2019, about 33 million episodes of RSV-induced acute lower respiratory infections (ALRI) occurred in children under 5 years of age. 1 in 5 episodes occurs in children aged 0 -6 months. 1

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

By the age of 2 almost all children will have been infected with RSV, with approximately 1/4-1/3 developing lower respiratory tract disease; 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]

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

RSV strains are grouped within a single serotype but are separated into 2 subgroups: RSV-A and RSV-B and both can cause severe disease. Both subgroups co-circulate during the RSV season, however the dominating subgroup is unpredictable and variable in annual outbreaks. [4], [5]

Number of deaths from the disease per year

In young children an estimated 101,400 deaths occur annually, 45,700 in infants under 6 months with 97% of these deaths occurring in LMICs. Furthermore <200,000 RSV-related deaths are estimated to occur in other age groups, mostly the elderly. [6], [7]

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

In-hospital CFR for children aged 0 to 60 months: 0.1 % in HICs, 0.6 %–0.8 % in LMICs, and 1.4 % in LICs. However, community mortality studies show a high and unmeasured burden of RSV deaths in children in LMICs e.g. 4 deaths occur in the community for every 1 in-hospital death in LMICs. [8]

Outbreak, epidemic or pandemic risk

Seasonal epidemics occur every year in the general population in most locations globally. Nosocomial outbreaks have been reported in several health care settings, including pediatric/neonatal intensive care units, adult stem cell transplant units, and adult

hematology/oncology units in LMICS. RSV outbreaks have also been reported in older adults in long-term care facilities. RSV is not a virus of pandemic potential. [3]

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

Currently there is no global or regional elimination goal.

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Benefits of the intervention

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

Current RSV immunization products protect against both subgroups of RSV. [9], [10]

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

For maternal RSVPreF: Vaccine efficacy against RSV-positive severe medically-attended LRTI at 180 days after birth was 70 % (50.6, 82.5) and 49.2% (31.4, 62.8) against RSV-positive medically attended LRTI. [11]

For nirsevimab: Efficacy against medically attended RSV-associated LRTI was 79% (68.5, 86.1). Efficacy against hospitalization for RSV-associated LRTI was 80.6% (62.3, 90.1) and efficacy against severe hospitalized RSV-associated LRTI was 78.5% (48.8,91.0). [12], [13]

Both products have been shown to have high, similar effectiveness when used in real-world situations.

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

The duration of protection is between 5-6 months. RSV antibody titers remained high 6 months after birth in infants born to mothers vaccinated with the maternal RSVPreF vaccine. Similarly, efficacy outcomes measured at 5 months after nirsevimab administration indicated protection at 5 months. 14, 15, 16

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Safety of the intervention

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

Adverse events after nirsevimab administration may include a rash, rash maculo-papular and rash papular. There may also be an injection site reaction including injection site pain, induration, edema and site swelling. Very rare cases of serious hypersensitivity reactions have been reported following nirsevimab administration, these reactions included urticaria, dyspnea, cyanosis, and/or hypotonia. 17

Recipients of the maternal RSVPreF vaccine may experience injection site pain, which is mild to moderate. Systemic symptoms, including muscle pain and headaches may also occur. 18

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). A numerical increase in hypertensive disorders of pregnancy were also observed among vaccine recipients (not statistically significant). In infants of vaccine recipients, low birth weight cases were higher compared to the placebo group (not statistically significant). Post-authorization safety evaluations from the first season of use in the US concluded that the RSVPreF vaccine is not associated with increased risk for preterm birth or SGA at birth. 15, 19

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Values and preferences

Perception of the target population on the risk of disease

RSV bronchiolitis is recognized by mothers in LMICs when they are shown videos of the condition. Name recognition of RSV is low in most LMICs, but there is caretaker awareness of the bronchiolitis syndrome in babies; prevention of this syndrome is desired by pregnant and lactating persons. 20

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Acceptability to stakeholders

Acceptability of the vaccine and of vaccination against the disease

The acceptability of maternal tetanus vaccines is generally high in LMICs. Acceptance of other maternal vaccines depends on the perception of safety to the infant. 21

Acceptability of RSV maternal vaccine is dependent on increasing the awareness of RSV. If key stakeholders are provided with reliable evidence to demonstrate the benefits of the RSVpre-F vaccine, it is likely to be acceptable. However, the cost of RSV vaccination is likely to influence how countries will prioritize its introduction relative to other vaccines or public health interventions. 3

For nirsevimab, 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. 22

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Financing & funding

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

If procuring through UNICEF SD: a box of 100 AD syringes with needles (0.5 ml) is priced at approximately $4.50, equating to $0.045 per syringe with needle; a box of 25 safety boxes (each with a 5-liter capacity) for about $20.26, resulting in approximately $0.81 per safety box. Each 5-liter safety box can hold around 100 syringes, leading to a disposal cost of approximately $0.008 per syringe. 23, 24

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. 25 The incremental cost to the healthcare system is estimated to be US$ 0.74 in LICs and US$ 2.02 in MICs. 26

Estimated vaccine financial cost per dose (in USD)

The current price range in HICs for nirsevimab in the public sector varies between US$ 231 and US$ 730 per dose and maternal RSVPreF vaccine ranges between US$ 205 and US$ 234 per dose. In the US the price for the two monoclonal antibodies is the same: US$556 per dose. 27, 28

Pfizer has made a public commitment to develop a multidose vial that will be available in the coming years at a supply and price for the Gavi-eligible market, which is expected to be low and similarly to other vaccines funded by Gavi. 27

PAHO revolving fund has negotiated a price for maternal RSVpreF vaccine for Latin American countries of US$ 49 per dose.
To date, no price commitment for LMICs for monoclonal antibodies has been made. 29

Estimated financial cost per person vaccinated (in USD)

Globally, the estimated cost per person vaccinated ranges between countries. In 2018, the reported cost of delivering a maternal vaccine ranged from US$ 0.55 to $0.64 for LICs, US$ 1.25 to US$ 6.55 for MICs, andUS$ 5.76 to US$ 39.87 in HICs. The UNICEF price estimate for delivering birth dose vaccines (BCG and the HepB vaccines) is US$ 2.34, and this gives an estimate of delivery costs for nirsevimab as a birth dose. 30, 31

In addition to these costs, the direct cost of the vaccines and mAb per dose will need to be included (currently unknown for LMICs).

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 vaccines was US$ 3.50 and the price of the mAb was US$ 3.50. 32

Given lower anticipated prices for maternal RSVpreF, immunization is expected to be more cost-effective than using nirsevimab. 33

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 mAbs were approved in the 2018 Gavi Vaccine Investment Strategy. These are to be re-visited at Gavi board in Q4 2025. Only the maternal vaccine has a Gavi price commitment currently and Gavi co-funding and other support is yet to be determined. 34, 35

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Market (feasibility)

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

There is currently one supplier for the maternal RSVPreF vaccine and two suppliers for monoclonal antibdoies. Detailed information on the different products can be found in the comparison table [36]

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Service delivery (feasibility)

Number of doses and timing of administrations

Both the maternal RSVPreF vaccine and the monoclonal antibodies require one dose.
The maternal vaccine is recommended for the 3rd trimester of pregnancy.
Nirsevimab is available in 2 weight-band dosages: 50mg for infants <5 kgs and 100mg for infants ≥ 5 kgs. It is recommended to be given to infants at birth or soon after. For countries choosing to take a seasonal approach with catch-up, older infants up to 12 months of age can be given a dose of nirsevimab just prior to or during the RSV season.
Clersovimab has one single dosage 105mg and is recommended to be given to infants at birth or before start of the RSV season.[37] [38]

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Logistics (feasibility)

Cold chain volume required per vaccine dose (in cm3)

Secondary packaging: Vaccine and diluent are packed separatetly in a box of 25 vials (25 doses) each. Dimensions: 8.6 x 8.6 x 4.1 cm. Cold chain requirements: 12.1 cm3/dose (in secondary packaging)

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Sources

1.
Li Y, Wang X, Blau DM, Caballero MT, Feikin DR, Gill CJ, et al. (2022). Global, regional, and national disease burden estimates of acute lower respiratory infections due to respiratory syncytial virus in children younger than 5 years in 2019: a systematic analysis. Lancet. 400(10319): 717–739. doi:10.1016/S0140-6736(22)00478-0.

2.
Glezen WP, Taber LH, Frank AL, Kasel JA (1986). Risk of primary infection and reinfection with respiratory syncytial virus. Am J Dis Child. 140:543–546. doi:10.1001/archpedi.1986.02140200053026.

3a.3b.3c.
Fleming JA, Baral R, Higgins D, Khan S, Kochar S, Li Y, et al. (2023). Value profile for respiratory syncytial virus vaccines and monoclonal antibodies. Vaccine. 41(Suppl 1):S7. doi:10.1016/j.vaccine.2022.09.081.

4.
Mufson MA, Orvell C, Rafnar B, Norrby E (1985). Two distinct subtypes of human respiratory syncytial virus. J Gen Virol. 66(Pt 10):2111–2124. doi:10.1099/0022-1317-66-10-2111.

5.

Borchers AT, Chang C, Gershwin ME, Gershwin LJ (2013). Respiratory syncytial virus—a comprehensive review. Clin Rev Allergy Immunol. 45:331–379. doi:10.1007/s12016-013-8368-9.

6.
Li Y, Wang X, Blau DM, Caballero MT, Feikin DR, Gill CJ, et al. (2022). Global, regional, and national disease burden estimates of acute lower respiratory infections due to respiratory syncytial virus in children younger than 5 years in 2019: a systematic analysis. Lancet. doi:10.1016/s0140-6736(22)00478-0.

7.
Du Y, et al. (2023). Global burden and trends of respiratory syncytial virus infection across different age groups from 1990 to 2019: a systematic analysis of the global burden of disease 2019 study. Int J Infect Dis. 135:70–76. doi:10.1016/j.ijid.2023.08.008.

8.
Li Y, Wang X, Blau DM, Caballero MT, Feikin DR, Gill CJ, et al. (2022). Global, regional, and national disease burden estimates of acute lower respiratory infections due to respiratory syncytial virus in children younger than 5 years in 2019: a systematic analysis. Lancet. doi:10.1016/s0140-

9.
European Medicines Agency (n.d.). Abrysvo: EU summary of product characteristics [product information document]. Amsterdam: EMA (https://www.ema.europa.eu/en/documents/product-information/abrysvo-epar-product-information_en.pdf, accessed 19 June 2025).

10.
European Medicines Agency (n.d.). Beyfortus: EU summary of product characteristics [product information document]. Amsterdam: EMA (https://www.ema.europa.eu/en/documents/product-information/beyfortus-epar-product-information_en.pdf, accessed 19 June 2025).

11.
Müller WJ, Madhi SA, Seoane Nuñez B, Baca Cots M, Bosheva M, Dagan R, et al. (2023). Nirsevimab for prevention of RSV in term and late-preterm infants. N Engl J Med. 388:1533–1534. doi:10.1056/NEJMc2214773.

12.

Griffin MP, Yuan Y, Takas T, Domachowske JB, Madhi SA, Manzoni P, et al. (2020). Single-dose nirsevimab for prevention of RSV in preterm infants. N Engl J Med. 383:415–425. doi:10.1056/NEJMoa1913556.

13.
Kampmann B, Madhi SA, Munjal I, Simões EAF, Pahud BA, Llapur C, et al. (2023). Bivalent prefusion F vaccine in pregnancy to prevent RSV illness in infants. N Engl J Med. 388:1451–1464. doi:10.1056/NEJMoa2216480.

14.
United States Food and Drug Administration (2023). Vaccines and Related Biological Products Advisory Committee meeting, 18 May 2023: FDA briefing document. Silver Spring (MD): US FDA (https://www.fda.gov/media/168185/download, accessed 20 June 2025).

15a.15b.
Kampmann B, Madhi SA, Munjal I, Simões EAF, Pahud BA, Llapur C, et al. (2023). Bivalent prefusion F vaccine in pregnancy to prevent RSV illness in infants. N Engl J Med. 388:1451–64.

16.
Simões EAF, Madhi SA, Muller WJ, Atanasova V, Bosheva M, Cabañas F, et al. (2023). Efficacy of nirsevimab against respiratory syncytial virus lower respiratory tract infections in preterm and term infants, and pharmacokinetic extrapolation to infants with congenital heart disease and chronic lung disease: a pooled analysis of randomized controlled trials. Lancet Child Adolesc Health. 7(3):180–89. doi:10.1016/S2352-4642(22)00321-2.

17.
FDA-Approved drugs (2024). United States Food and Drug Administration (FDA) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761328s005lbl.pdf, accessed 20 June 2025).

18.
FDA-Approved drugs (2024). United States Food and Drug Administration (FDA) (https://www.fda.gov/media/168889/download?attachment, accessed 20 June 2025).

19.

DeSilva M (2024). RSVpreF vaccine, preterm birth, and small for gestational age at birth: preliminary results from the Vaccine Safety Datalink. ACIP meeting, October 2024 (https://www.cdc.gov/acip/downloads/slides-2024-10-23-24/03-RSV-Mat-Peds-DeSilva-508.pdf, accessed 20 June 2025).

20.
Limaye RJ, Sauer M, Njogu R, Singh P, Fesshaye B, Karron RA (2023). Characterizing attitudes toward maternal RSV vaccines among pregnant and lactating persons in Kenya: key considerations for confidence. J Pediatric Infect Dis Soc. 12:638–41.

21.
SAGE EtR tables (2024). September 2024. Geneva: World Health Organization (https://terrance.who.int/mediacentre/data/sage/SAGE_eYB_Sept2024.pdf, accessed 20 June 2025).

22.
Limaye RJ, Sauer M, Njogu R, Singh P, Fesshaye B, Karron RA (2023). Characterizing attitudes toward maternal RSV vaccines among pregnant and lactating persons in Kenya: key considerations for demand generation efforts for vaccine acceptance. J Pediatric Infect Dis Soc. 12:638–41.

23.
UNICEF (2024). Standard costs of fully vaccinating a child. New York: United Nations Children's Fund (https://www.unicef.org/media/161751/file/Standard%20costs%20of%20fully%20vaccinating%20a%20child_U accessed 20 June 2025).

24.
UNICEF (2025). AD syringe with needle [website]. New York: United Nations Children's Fund (https://supply.unicef.org/s0002016.html?utm, accessed 20 June 2025).

25.
UNICEF (2025). Safety boxes [website]. New York: United Nations Children's Fund (https://supply.unicef.org/s0782208.html?utm, accessed 20 June 2025).

26.

Mahmud S, Baral R, Sanderson C, Pecenka C, et al. (2023). Cost-effectiveness of pharmaceutical strategies to prevent respiratory syncytial virus disease in young children: a decision-support model for use in low-income and middle-income countries. BMC Med. 21(1). doi:10.1186/s12916-023-02827-5.

27a.27b.
World Health Organization (2024). WHO global market study – RSV immunization products. Geneva: World Health Organization (https://cdn.who.int/media/docs/default-source/immunization/mi4a/who_global_market_study_on_rsv_immunization_products_sep-2024.pdf, accessed 20 June 2025).

28.
Pan American Health Organization (2025). PAHO vaccine prices for 2025. Washington (DC): PAHO (https://www.paho.org/sites/default/files/2025-02/prices-vac-2025-eng-27-feb-25.pdf, accessed 20 June 2025).

29.
United States Centers for Disease Control and Prevention (2025). CDC vaccine price list for childhood vaccines. Atlanta (GA): US CDC (https://www.cdc.gov/vaccines-for-children/php/awardees/current-cdc-vaccine-price-list.html, accessed 20 June 2025).

30.
Procter SR, Salman O, Pecenka C, Gonçalves BP, Paul P, Hutubessy R, et al. (2020). A review of the costs of delivering maternal immunisation during pregnancy. Vaccine. 38(40):6199. doi:10.1016/j.vaccine.2020.07.050.

31.
UNICEF (2024). Costs of fully vaccinating a child. New York: United Nations Children’s Fund (https://www.unicef.org/media/161751/file/Standard%20costs%20of%20fully%20vaccinating%20a%20child_U accessed 20 June 2025).

32.
Mahmud S, Baral R, Sanderson C, Pecenka C, Jit M, Li Y, et al. (2023). Cost-effectiveness of pharmaceutical strategies to prevent respiratory syncytial virus disease in young children: a decision-support model for use in low-income and middle-income countries. BMC Med. 21:138.

doi:10.1186/s12916-023-02827-5.

33.

Universal vaccine decision-support model [website]. Geneva: World Health Organization; 2025 (https://sites.google.com/view/univac, accessed 20 June 2025).

34.

Gavi, the Vaccine Alliance (2018). Report to the Board, 28–29 November 2018: vaccine investment strategy. Geneva: Gavi, the Vaccine Alliance (https://www.gavi.org/sites/default/files/board/minutes/2018/28-nov/docs/08%20-%20Vaccine%20Investment%20Strategy%20document.pdf, accessed 20 June 2025).

35.

Gavi, the Vaccine Alliance (2025). Gavi welcomes first-ever prequalification of maternal RSV vaccine. Geneva: Gavi, the Vaccine Alliance (https://www.gavi.org/news/media-room/gavi-welcomes-first-ever-prequalification-maternal-rsv-vaccine, accessed 20 June 2025).

36.

Detailed product comparison sheet

37.

(to be replaced with Position paper)

38.

World Health Organization (2024). Meeting of the Strategic Advisory Group of Experts on Immunization (SAGE), December 2024. Wkly Epidemiol Rec. 99(49):719–40 (https://www.who.int/publications/i/item/who-wer9949-719-740, accessed 20 June 2025).