How Gavi support for RSV immunisation will advance health equity

Respiratory syncytial virus (RSV) causes severe illness in millions of young children each year.[1] Globally, it is estimated that over 100 000 children younger than 5 years die each year from RSV; 97% of these deaths occur in low-income and middle-income countries (LMICs).[2] Approximately 45% of RSV-associated deaths occur in infants younger than 6 months.[2] Mortality, as well as severe morbidity, could be prevented through maternal vaccination or through passive immunisation of infants after birth. Preventing RSV disease could also reduce the risk of superimposed bacterial pneumonia.

Gavi, the Vaccine Alliance, is an international partnership created to improve access to new and underused vaccines for children living in the world's poorest countries. In supplying lifesaving vaccines to more than 1 billion children, it is estimated that Gavi support has prevented more than 17 million deaths.[3,4]

By supporting RSV prevention strategies, Gavi could save many more lives. In 2018, the Gavi board identified RSV as a key priority for further expansion of the Gavi portfolio of vaccines, voicing support of products to protect infants including maternal vaccines and long-acting monoclonal antibodies.[5] This decision was contingent upon the availability of a licensed product, WHO prequalification, WHO Strategic Advisory Group of Experts (SAGE) recommendation, meeting the financial assumptions from the initial investment case presented, and the availability of funds.[6] Since that time, two highly effective products, the RSVpreF maternal vaccine and the RSV monoclonal antibody nirsevimab, have been licensed and implemented in many high-income and upper-middle-income countries, with other products in late-stage development.[7] In 2024, SAGE recommended that "all countries introduce products for the prevention of severe RSV disease in infants".[6]

The RSVpreF vaccine single dose vial for maternal vaccination has recently been WHO prequalified, with prequalification of the multidose vial anticipated in 2026, a necessary prerequisite for affordability in LMICs.[8] RSV immunisation has been successfully introduced in high-income countries, resulting in major public health impact.[9,10] Because political shifts in high-income countries have put pressure on the financial support for global immunisation programmes in countries with the highest mortality rates, and on the Gavi budget, the implementation of RSV immunisation could remain delayed and roll-out in LMICs could stall. Although recognising the substantial budget challenges facing the Gavi board, we reiterate the value of prioritising support for the RSV interventions that meet the criteria of the Gavi investment case.

As with the other diseases within the Gavi strategy, Africa and south Asia bear the highest burden of RSV disease, yet currently have no access to RSV immunisation through public health systems. Addressing this gap will advance Gavi's commitment to equity. The tools are available. Investment in RSV prevention will help reduce premature mortality and achieve Sustainable Development Goal target 3.2: ending preventable deaths of newborns and children younger than five by 2030. An RSV programme would also align with the goals of WHO, UNICEF, and other global agencies to strengthen maternal and child health and reduce hospitalisation and deaths from respiratory diseases, the leading cause of mortality for children younger than 5 years worldwide. Preventing RSV disease during infancy will also free up health system capacity to treat other diseases.

As part of its mission to save lives and protect people's health by increasing equitable and sustainable use of vaccines, we call on Gavi's leadership to ensure equitable access to RSV prevention for all children—no matter where they are born.

Published Online
June 25, 2025
https://doi.org/10.1016/S0140-6736(25)01117-1

This Correspondence has been endorsed by 44 leading scientific and societal organisations wordwide (appendix pp 1–2). LJB has regular interaction with pharmaceutical and other industrial partners, but has not received personal fees or other personal benefits; and is a board member of three non-profit foundations (ReSViNET, INFECT-NL, and Vrienden UMC Utrecht). LJB also reports that University Medical Centre Utrecht has received major funding (>€100 000 per industrial partner) for investigator initiated studies from AstraZeneca, Sanofi, Janssen, Pfizer, Merck Sharp & Dohme (MSD), and MeMed Diagnostics; has received major funding from The Gates Foundation; has received major funding as part of the public—private partnership IMI-funded RESCEU and PROMISE projects with partners GlaxoSmithKline (GSK), Novavax, Janssen, AstraZeneca, Pfizer, and Sanofi; has received major funding from Julius Clinical for participating in clinical studies sponsored by AstraZeneca, Merck, and Pfizer; and has received minor funding (€1000–25 000 per industrial partner) for consultation, data safety monitoring board membership, or invited lectures from Ablynx, Bavaria Nordic, GSK, Novavax, Pfizer, Moderna, AstraZeneca, MSD, Sanofi, and Janssen. CP reports grants from the Gates Foundation; and participation on a data safety monitoring board or advisory board for WHO and Gavi, the Vaccine Alliance. FM-T reports grants or contracts from Sanofi–AstraZeneca, GSK, and Pfizer; consulting fees from GSK, Pfizer, Sanofi Pasteur, Janssen Pharmaceuticals, MSD, CSL Seqirus, Biofabri, and AstraZeneca; support for attending meetings or travel from Pfizer, MSD, GSK, and Sanofi; is a member of ETAGE – WHO Europe, coordinator of the Spanish Pediatric Critical Trials Network, and coordinator of WHO Collaborating Centre for Vaccine Safety of Santiago de Compostela; and is Principal investigator in randomised controlled trials of Ablynx, Abbot, Seqirus, Sanofi Pasteur MSD, Sanofi Pasteur, Cubist, Wyeth, Merck, Pfizer, Roche, Regeneron, Jansen, Medimmune, Novavax, Novartis, and GSK, with honoraria paid to his institution. HJZ reports grants or contracts from Pfizer, MSD, and Sanofi; payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing, or educational events from Pfizer; participation on a data safety monitoring board or advisory board for Moderna and Sanofi; and was past chair for the WHO Technical Advisory Group on new RSV preventive interventions. MJG reports grants and support for attending meetings from the Gates Foundation. SAM reports grants or contracts from the Gates Foundation, GSK, Pfizer, Minervax, Merck, Providence, and Gritstone; honoraria for lectures from GSK; and participation on a data safety monitoring board or advisory board from PATH, CAPRISA, and Bavarian Nordic. All other authors declare no competing interests.

See Online for appendix

*Hellen C Barsosio, *Louis J Bont, Michelle J Groome, Ruth A Karron, Leyla Kragten-Tabatabaie, Shabir A Madhi, Federico Martinón-Torres, Clint Pecenka, Heather J Zar*

l.bont@umcutrecht.nl

Centre for Global Health Research, Kenya Medical Research Institute, Kisumu, Kenya (HCB); Wilhelmina Children's Hospital, University Medical Centre Utrecht, Utrecht University, Utrecht 3584EA, Netherlands (LJB); South African Medical Research Council Vaccines and Infectious Diseases Analytics Research Unit, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa (MJG, SAM); Department of International Health, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD, USA (RAK); ReSViNET Foundation, Zeist, Netherlands (LJB, LK-T); Department of Science and Technology/National Research Foundation: Vaccine Preventable Diseases, University of the Witwatersrand, Johannesburg, South Africa (SAM); Translational Pediatrics and Infectious Diseases, Hospital Clínico Universitario de Santiago and University of Santiago de Compostela, Santiago de Compostela, Galicia, Spain (FM-T); Genetics, Vaccines and Infectious Diseases Research Group, Instituto de Investigación Sanitaria de Santiago de Compostela, Santiago de Compostela, Galicia, Spain (FM-T); WHO Collaborating Centre for Vaccine Safety, Santiago de Compostela, Galicia, Spain (FM-T); Centro de Investigación Biomédica en Red de Enfermedades Respiratorias, Instituto de Salud Carlos III, Madrid, Spain (FM-T); Center for Vaccine Innovation and Access, PATH, Seattle, WA, USA (CP); Department of Paediatrics and Child Health, Red Cross Children's Hospital, Cape Town, South Africa (HJZ); MRC Unit on Child and Adolescent Health, University of Cape Town, Cape Town, South Africa (HJZ)

1 Mazur NI, Caballero MT, Nunes MC. Severe respiratory syncytial virus infection in children: burden, management, and emerging therapies. *Lancet* 2024; **404:** 1143–56.

2 Li Y, Wang X, Blau DM, et al. Global, regional, and national disease burden estimates of acute lower respiratory infections due to respiratory syncytial virus in children younger than 5 years in 2019: a systematic analysis. *Lancet* 2022; **399:** 2047–64.

3 Gavi, The Vaccine Alliance. Our Impact. 2025. www.gavi.org/programmes-impact/our-impact (accessed May 15, 2025).

4 Gavi, The Vaccine Alliance. Five years to save 8 million lives: everything you need to know about Gavi's Investment Opportunity. 2024. https://www.gavi.org/vaccineswork/five-years-save-8-million-lives-everything-you-need-know-about-gavis-investment (accessed May 15, 2025).

5 Gavi, The Vaccine Alliance. 06a - Annex C: Respiratory Syncytial Virus Investment Case. 2018. https://www.gavi.org/sites/default/files/document/ppc-meeting-18-19-october-2018---vis-06a---annex-c--respiratory-syncytial-virus-investment-casepdf.pdf (accessed May 28, 2025).

6 PATH. RSV vaccine and mAb snapshot. 2025. https://www.path.org/our-impact/resources/rsv-vaccine-and-mab-snapshot/ (accessed May 15, 2025).

7 WHO Bulletin. Meeting of the Strategic Advisory Group of Experts on Immunization, September 2024: conclusions and recommendations. 2024. https://www.who.int/publications/i/item/who-wer9949-719-740 (accessed May 28, 2025).

8 Gavi, The Vaccine Alliance. Gavi welcomes first-ever prequalification of a maternal RSV vaccine. 2025. https://www.gavi.org/news/media-room/gavi-welcomes-first-ever-prequalification-maternal-rsv-vaccine (accessed May 15, 2025).

9 Pérez Marc G, Vizzotti C, Fell DB, et al. Real-world effectiveness of RSVpreF vaccination during pregnancy against RSV-associated lower respiratory tract disease leading to hospitalisation in infants during the 2024 RSV season in Argentina (BERNI study): a multicentre, retrospective, test-negative, case–control study. *Lancet Infect Dis* 2025; published online May 5. https://doi.org/10.1016/S1473-3099(25)00156-2.

10 Moline HL, Toepfer AP, Tannis A, et al. Respiratory syncytial virus disease burden and nirsevimab effectiveness in young children from 2023–2024. *JAMA Pediatr* 2025; **179:** 179–87.