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RESPIRATORY SYNCYTIAL VIRUS: A SCOPING REVIEW OF PATHOPHYSIOLOGY, EPIDEMIOLOGY, ECONOMIC BURDEN, AND ADVANCES IN PREVENTION WITH IMPLEMENTATION CHALLENGES

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ABSTRACT

Background: Respiratory Syncytial Virus (RSV) is a leading cause of lower respiratory tract infections globally, disproportionately affecting infants and older adults, with over 99% of childhood deaths occurring in low- and middle-income countries (LMICs). Despite its substantial burden, RSV remains underrepresented in national immunisation programmes, particularly in India. **Methods:** This scoping review followed the PRISMA framework. PubMed, Scopus, and Google Scholar were searched for literature published between 2015 and 2025 using terms including "RSV epidemiology," "RSV vaccine," "monoclonal antibody RSV," "RSV burden India," and "RSV implementation." Studies addressing RSV pathophysiology, burden, prevention, and implementation in any setting were included; non-English publications and studies unrelated to human RSV disease were excluded. Findings were synthesised narratively. **Results:** RSV causes 33.1 million acute lower respiratory infections and up to 101,400 deaths annually in children under five, with LMICs bearing over 95% of this burden. India-specific data reveal RSV detection rates of 5–54% in hospitalised children. Recent approvals of nirsevimab, Abrysvo®, Arexvy®, and mResvia offer significant preventive efficacy (70–90%), yet affordability, cold chain requirements, regulatory delays, and vaccine hesitancy impede equitable access, especially in LMICs. **Conclusion:** RSV prevention now has a robust scientific foundation, but translating these advances into public health impact requires context-specific implementation strategies. India and LMICs must urgently address surveillance gaps, cost barriers, and programmatic integration within existing immunisation frameworks.

KEYWORDS: Respiratory Syncytial Virus; RSV vaccine; nirsevimab; scoping review; LMICs; immunization.

INTRODUCTION

Respiratory Syncytial Virus (RSV) is a well-established etiological agent responsible for a significant proportion of lower respiratory tract infections (LRTIs), primarily affecting young children and the elderly worldwide.[1] RSV is the second most prominent cause of infant death following the neonatal stage, with over 99% of these fatalities occurring in LMICs, where it functions as a "silent killer" due to inadequate surveillance and underestimated virulence.[1] In adults over 60, the disease burden is analogous to seasonal influenza, underscoring its cross-lifespan impact.

RSV is a negative-sense RNA virus in the *Orthopneumovirus* genus. Its approximately 15,200-nucleotide genome encodes 11 proteins, including envelope glycoproteins G (cell attachment) and F (membrane fusion), both key antibody targets. RSV comprises two antigenic groups—A (14 genotypes including GA2, ON1) and B (27 genotypes including BA1, SAB4)—classified by G protein reactivity.

Vaccine development was historically hampered by the failed formalin-inactivated RSV (FI-RSV) trial in the 1960s, which caused enhanced respiratory disease (ERD) and two deaths in children under two years, attributable to weak neutralising antibodies and a Th2-biased T-cell

response. This setback, however, yielded critical insights: the pre-fusion conformation of the F protein is essential for protective immunity. A subsequent paradigm shift towards rational, structure-based vaccine design targeting the pre-fusion F protein has underpinned recent breakthroughs in both vaccine and monoclonal antibody (mAb) development.[1]

METHODS

This scoping review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA). Three databases—PubMed, Scopus, and Google Scholar—were searched for literature published between January 2015 and April 2025. Search terms included: "Respiratory Syncytial Virus epidemiology," "RSV vaccine efficacy," "RSV monoclonal antibody," "RSV burden India," "RSV LMICs," "nirsevimab," "RSV implementation challenges," and "RSV prevention." Studies were included if they addressed RSV pathophysiology, global or regional disease burden, prevention strategies (vaccines or mAbs), economic impact, or implementation challenges in human populations. Non-English publications, animal studies, and articles unrelated to human RSV disease were excluded. Data from eligible sources were charted and synthesised using a narrative approach, with particular attention to findings relevant to India and LMICs. No formal quality appraisal was applied.

Pathophysiology and Clinical Manifestations of RSV Infection

RSV infection ranges from mild upper respiratory illness to severe bronchiolitis, pneumonia, or croup, particularly in infants. Following a 3–5 day incubation, the virus spreads from the nasopharynx to the lower respiratory tract. Clinical indicators of RSV-positive LRTI include wheezing, chest indrawing, rapid breathing, and crackles. Severe infection in the first year of life significantly increases long-term risk of recurrent wheeze and asthma, with re-infections occurring throughout life.[1,2]

In adults, RSV is typically mild but can be severe in frail elderly individuals and those with chronic pulmonary, circulatory, or immunocompromising conditions. A two-year study reported 60-day mortality rates of 7.3% in haematopoietic stem cell transplant recipients, 13.3% in solid-organ transplant patients, and 12.8% in COPD patients with RSV infection—mortality rates comparable to influenza in these groups, reinforcing the rationale for expanded prevention strategies across age groups.[1]

Global and Regional Epidemiology of RSV

RSV is the primary driver of acute lower respiratory infection (ALRI) morbidity and mortality in children under five globally. LMICs report approximately 30 million cases annually versus 2.8 million in high-income countries (HICs). Globally, RSV causes an estimated 3.2–3.6 million hospitalisations and 59,600–101,400 in-hospital deaths annually. Infants under six months are disproportionately affected, accounting for approximately 1.4 million hospitalisations and 27,300 deaths in 2019, representing about 50% of all paediatric RSV deaths and 36–39% of hospital admissions.[1,3,4] Over 95% of RSV-associated ALRIs and deaths occur in LMICs.[3]

In older adults, RSV causes approximately 64 million infections globally each year.[5] In the United States alone, RSV accounts for 60,000–160,000 hospitalisations and 6,000–10,000 deaths annually among those aged ≥65 years.[3] A 2019 meta-analysis estimated 5.2 million confirmed RSV-ARI cases in adults ≥60 years in HICs, resulting in 470,000 hospitalisations and 33,000 deaths.[5] The 2023–2024 US RSV hospitalisation peak reached 4.2 per 100,000, exceeding prior seasonal rates.[6]

RSV epidemics follow distinct seasonality: September–December in the northern hemisphere and March–June in the southern hemisphere, with tropical regions experiencing up to 10-month activity peaks during rainy seasons.[1] The COVID-19 pandemic significantly disrupted RSV seasonality through non-pharmaceutical interventions, leading to "immunity debt" and altered post-pandemic patterns, with more severe disease observed in older children.[7,8] Recent Canadian data (May 2025) indicate the highest RSV detection proportions in the 65–84 age group.[9]

India-specific data reveal considerable heterogeneity: RSV detection rates range from 5% to 54% in hospitalised children, with molecular methods yielding 15–22% positivity. A community cohort in Ballabhgarh recorded an incidence of 14.9% in children aged 0–10 years (2012–2014), while hospitalisation incidence in infants was 7.4 per 1,000 child-years. Seasonality varies regionally—winter peaks predominate in North India and Kolkata, whereas Odisha shows a rainy season–winter bimodal pattern.[1] These data highlight the urgent need for systematic national surveillance to inform India-specific RSV policy.

Latest global and India-specific RSV burden estimates are summarised in Table 1.

Table 1: Latest Global and India-Specific RSV Burden Estimates (2019–2025)

Category	Population Group	Metric	Estimate (Year/Period)
Global Burden	Children <5 years	Annual ALRI episodes	33.1 million (2019)
		Annual hospitalisations	3.2–3.6 million (2019)
		Annual deaths	59,600–101,400 (2019)
	Infants 0–6 months	Proportion of paediatric deaths	~50% (2019)
		Proportion of hospitalisations	36–39% (2019)
		ICU admission rate	5% (infants <6 months)
	LMICs (children)	Proportion of global ALRI/deaths	>95%
	Adults >60 years (US)	Annual hospitalisations	60,000–160,000
		Annual deaths	6,000–10,000
	Adults >60 years (HICs)	Confirmed ARI cases	5.2 million (2019)
		In-hospital deaths	33,000 (2019)
India-Specific Burden	Children <5 years	Hospital RSV detection rates	5–54% (variable)
		Molecular detection rates	15–22%
	Children (Ballabhgarh)	Incidence (0–10 years)	14.9% (2012–2014)
	Infants (Ballabhgarh)	Hospitalisation incidence	7.4 per 1,000 child-years
	Children 0–2 years (West Bengal)	RSV positivity in ILI	12.6% (April 2022–March 2023)
Seasonality in India	North India	Predominant peak	Winter
	Odisha	Predominant peak	Rainy season, followed by winter
	Kolkata	Predominant peak	November–February

Economic Burden of RSV Infection

RSV imposes a substantial economic burden globally, particularly in LMICs. Direct medical costs in LMICs exceed USD 3 billion, with indirect costs contributing 36.7% and direct non-medical costs 8.7% to the total.[1] Globally, RSV causes approximately 1.2 million DALYs and costs an estimated USD 5.4 billion annually, with LMICs bearing 55% of hospitalisation costs.[10]

In HICs, the burden is also significant. Among Americans aged ≥60 years, annual costs reach USD 6.6 billion, with hospitalised cases (4% of total) accounting for 94% of USD 2.9 billion in direct medical costs.[11] RSV-related LRTI in US infants under 12 months is estimated to cost USD 1.6–2.4 billion annually.[12,13] Preventive vaccination demonstrably reduces hospitalisation costs and improves quality of life in high-risk elderly populations.[14]

For India and LMICs, the economic case for RSV prevention is compelling: the comparable burden to seasonal influenza—for which vaccination is already cost-effective—supports investment in RSV immunisation. Economic evaluations must, however, incorporate indirect costs, productivity losses, and out-of-pocket expenditure, which are disproportionately borne by households in resource-limited settings.

Advances in RSV Prevention: Vaccines and Monoclonal Antibodies

The paradigm shift towards pre-fusion F protein–targeted vaccine design has yielded a pipeline of candidates across multiple platforms. By 2022, 33 RSV prevention candidates were in clinical development, with two vaccines now licensed for use.[1,15]

Monoclonal Antibodies (mAbs)

Monoclonal antibodies provide immediate passive immunity, particularly valuable for infants under six months who are at highest risk of severe RSV before active vaccines can be deployed.

- **Nirsevimab (Beyfortus™):** A human mAb with an extended half-life targeting the pre-fusion F protein, approved by the EMA (November 2022) and FDA (July 2023) for infants in their first RSV season. Phase 2/3 trials demonstrated 70–75% efficacy against medically attended RSV LRTI and 62–78% against hospitalisation. Real-world US data (2023–2024) showed 90% effectiveness against RSV hospitalisation.[16] A 2025 meta-analysis found nirsevimab reduced RSV-related hospitalisation by 83%, ICU admission by 81%, and LRTI by 75% in infants.[17] Six-month data from the HARMONIE study showed an 82.7% reduction in RSV hospitalisations, and Spain's 2024–2025 immunisation programme demonstrated a 69% decrease in infant RSV hospitalisations compared to the pre-nirsevimab 2022–2023 season.[18]
- **Clesrovimab (MK-1654):** Targeting Site IV on the RSV F protein, the Phase 2b/3 CLEVER trial demonstrated a 60.4% reduction in medically attended LRTI and an 84.2% reduction in hospitalisations by day 150. The SMART trial

confirmed comparable safety and efficacy to palivizumab in high-risk infants.[19]

- **RSM01:** An investigational mAb in development specifically for LMICs, targeting a price point under USD 5 per dose to ensure affordability. Phase 1 results were pending as of 2022.[1]
- **Palivizumab biosimilar:** Under development via public-private partnership, with needle-free administration and potential cost savings through dose reduction.[1]

Live-Attenuated Vaccines (LAVs)

LAVs replicate natural infection, inducing mucosal and cellular immunity. Phase 1 trials have demonstrated acceptable safety without vaccine-enhanced disease. Pooled efficacy estimates from five candidates reached 88% against RSV LRTI and 67% against RSV acute respiratory illness. Intranasal delivery is particularly advantageous for older infants in LMICs. Key candidates include RSV ANS2/41313/11314L and MV-012-968.[1]

Subunit Vaccines

Focused on the pre-fusion F protein to avoid the ERD risk associated with earlier post-fusion approaches, eight subunit vaccine candidates are in development, primarily targeting older adults and pregnant women.

- **Abrysvo® (Pfizer/RSVpreF):** A bivalent, unadjuvanted pre-fusion F vaccine approved by the FDA in May 2023 for adults ≥60 years, August 2023 for pregnant individuals (32–36 weeks' gestation) to protect infants from birth to six months, and October 2024 for at-risk adults aged 18–59 years. Real-world data (2023–2024) indicate approximately 79% effectiveness against RSV-related emergency department visits and 73% against hospitalisations in adults ≥60 years.[20] Maternal vaccination reduced infant RSV-LRTD risk by 51% within six months.[21]
- **Arexvy® (GSK/RSVpreF3):** An AS01E-adjuvanted pre-fusion F vaccine approved by the FDA in May 2023 for adults ≥60 years and June 2024 for those aged 50–59 at increased risk.[15,21] Real-world data (2023–2024) show approximately 77% effectiveness against RSV-related emergency department visits and 83% against hospitalisations in adults ≥60 years. Clinical trial data demonstrated protection against symptomatic RSV-LRTD for approximately 23 months.[20]
- **DS-Cav1 (NIAID/NIH):** A stabilised pre-fusion F subunit vaccine that demonstrated significant season-long increases in neutralising activity in Phase 1 trials, establishing proof of concept for structure-based RSV vaccine design.[1]

mRNA Vaccines

- **mResvia (Moderna/mRNA-1345):** Using the same lipid nanoparticle platform as SpikeVax, this vaccine encodes stabilised RSV pre-fusion F protein. FDA-approved in May 2024 for adults ≥60 years, it demonstrated approximately 80% efficacy against symptomatic RSV at four months and approximately 56% at one year.[20,21] Moderna is pursuing combination with hMPV and parainfluenza type 3 vaccines for paediatric use.[1]

Recombinant Vector Vaccines

- **MVA-BN-RSV (Bavarian Nordic):** Expressing RSV surface and intracellular antigens, this vaccine showed a 79% reduction in symptomatic RSV infection in a Phase 2a challenge study.[1]
- **Ad26.RSV.preF (Johnson & Johnson):** The Phase 3 EVERGREEN trial is ongoing in 23,000 adults ≥60 years across two RSV seasons. The CYPRESS study demonstrated 80% efficacy against RSV LRTI in older adults, earning FDA Breakthrough Therapy designation.[1]

Table 2 summarises the approved RSV prevention products and their real-world effectiveness.

Table 2: Approved RSV Prevention Products (2022–2025).

Product (Developer)	Type	Target Population	Approval (FDA/EMA)	Key Real-World Effectiveness (2023–2025)
Nirsevimab/Beyfortus™ (Sanofi/AstraZeneca)	Monoclonal Antibody	Infants (first/second RSV season)	EMA: Nov 2022; FDA: Jul 2023	83% reduction in RSV hospitalization (<12 months); 90% effectiveness (US, 2023–2024); 69% reduction in Spain (2024–2025)[16–18]
Abrysvo® (Pfizer)	Subunit Vaccine	Adults ≥60 years; pregnant (32–36 wGA); adults 18–59 at risk	FDA: May 2023 (≥60), Aug 2023 (maternal), Oct 2024 (18–59)	79% against ED visits; 73% against hospitalizations (adults ≥60); 51% reduction in infant RSV-LRTD (maternal)[21]
Arexvy® (GSK)	Subunit Vaccine	Adults ≥60 years; adults 50–59 at risk	FDA: May 2023 (≥60), Jun 2024 (50–59)	77% against ED visits; 83% against hospitalizations (adults ≥60)[16,21,22]
mResvia (Moderna)	mRNA Vaccine	Adults ≥60 years	FDA: May 2024	~80% efficacy at 4 months; ~56% at 12 months[1,21]

Challenges and Strategies for Equitable Implementation

Affordability and Access

Affordability remains the most critical barrier to RSV prevention in LMICs. The maternal RSVpreF vaccine costs approximately USD 320 per dose, while the full palivizumab course costs approximately USD 7,600.[1,22] Although modelling studies support cost-effectiveness in LMICs, current market prices are prohibitive for national immunization programmes without external financing or tiered pricing mechanisms. RSM01, targeting under USD 5 per dose, represents a deliberate effort to address this gap.[1]

Structural access barriers include: (i) absence of efficacy data from high-burden countries, complicating local adoption decisions; (ii) regulatory drug lag, with approval delays of 2–5 years in sub-Saharan Africa and South Asia relative to HICs; (iii) cold chain dependency (2–8°C storage) and last-mile delivery challenges in remote settings; and (iv) insufficient local RSV burden data to build the political and economic case for programme investment.[1,22]

Viral Resistance and Surveillance

Viral resistance poses a growing concern for mAb-based prophylaxis, as demonstrated by the failure of suptavumab due to a naturally occurring RSV-B mutation. Although current mAbs target highly conserved epitopes, continuous genomic surveillance is essential to detect emerging resistance mutations, characterise transmission dynamics, and identify superspreading events. Recent reports of nirsevimab-resistant RSV-B breakthrough infections underscore the urgency of real-time molecular surveillance, particularly in high-burden settings.[1,23] mAb cocktail strategies may offer resilience against resistance, though logistical and cost barriers require resolution.

Coexistence of Prevention Modalities

Different prevention approaches are likely to complement rather than replace one another. mAbs offer longer protection and greater flexibility for both premature and full-term infants, functioning as a safety net when maternal vaccination is incomplete or unavailable. Maternal vaccination provides broad infant protection and an alternative for caregivers who prefer not to directly vaccinate newborns, while also serving as a contingency against mAb resistance. The relative uptake of each modality will be determined by comparative efficacy, delivery infrastructure, cost, and community acceptability. Palivizumab may remain relevant in high-risk infant populations until extended half-life mAbs become widely accessible.[1]

Vaccine Hesitancy and Public Trust

Vaccine hesitancy is a significant implementation challenge in India and other LMICs, amplified by COVID-19–related misinformation, cultural beliefs, and institutional distrust. Specific concerns include fears about side effects, doubts regarding vaccine ingredients, and scepticism about government health agendas.[1,24] In India, root causes include perceived inadequacy of the healthcare system, fear of adverse events, and low confidence in vaccine effectiveness.[24]

Evidence-based strategies to address hesitancy—drawn from LMIC experience—include trust-building through community and religious leaders, leveraging credible sources such as WHO and healthcare providers, targeted behavioural change communication, and counter-misinformation campaigns via digital platforms.[1,25]

Long-Term Health Impacts and Emerging Research Directions

Severe RSV infection in infancy is associated with long-term respiratory morbidity, including recurrent wheeze and asthma. In elderly individuals, RSV exacerbates chronic conditions and increases downstream healthcare utilization.[2,7]

Emerging research is expanding the RSV agenda beyond prevention: (i) *Microbiome interactions*—early-life RSV infection may alter the gut microbiome, increasing allergic disease risk, with particular implications for premature infants;[26] (ii) *Climate change*—environmental factors including temperature and precipitation influence RSV detection timing, warranting integration of climate data into surveillance systems;[8,27] and (iii) *Co-infections*—RSV frequently co-circulates with influenza and SARS-CoV-2; 2023–2024 data indicate that RSV patients in emergency departments required more respiratory support and experienced higher in-hospital mortality than those with other respiratory viruses, highlighting the need for multipathogen diagnostic and treatment frameworks.[28,29]

DISCUSSION

This scoping review synthesizes evidence on RSV burden, prevention, and implementation challenges, with particular relevance to India and LMICs. Several critical insights emerge.

Burden asymmetry and surveillance gaps: The global burden of RSV is heavily concentrated in low- and middle-income countries accounting for over 95% of RSV mortality. Detection rates vary widely more than tenfold across the studies. Not always due to epidemiological differences but due to the diagnostic methods like antigen testing versus RT-PCR and gaps in infrastructures enabling surveillance. The surveillance systems remain fragmented in India and there is lack of a nationally representative RSV surveillance system. Integration of RSV surveillance into Integrated Disease Surveillance Programme (IDSP) is imperative in making evidence based public health decisions.

Comparative prevention strategies: Maternal vaccination and infant monoclonal antibody (mAb) prophylaxis represent complementary interventions

targeting different access gaps. A combined approach using maternal vaccination and infant mAb provide a pragmatic solution within the Universal Immunization Programme (UIP). This approach addresses the incomplete antenatal care coverage that we see in India and LMICs. Policy makers must prioritize formal health economic evaluations using India-specific parameters.

Efficacy versus real-world effectiveness: Most data on efficacy for approved RSV interventions (70-90%) are from high income countries (HICs) and effectiveness data from LMICs are limited. These data gaps are reflected in policy decisions. Nirsevimab which have shown effectiveness in Spain and USA may not apply directly apply to countries like India. Factors like higher infection burden, overcrowding, limited access to health care and malnutrition may influence how these interventions performs thus highlighting need for local evidence.

Policy and practice implications for India and LMICs: RSV prevention in India and LMICs needs a multi-step approach. First, RSV vaccines should be made affordable, requiring price negotiations and transfer of technology agreements to be mediated by government and department of health and family welfare. This had been done before in India in case of pneumococcal and rotavirus vaccines. Second, the cold chain system under Universal Immunization Programme (UIP) can be utilized for vaccine deployment and reduce additional costs. Third, RSV should be incorporated into IDSP so reliable burden data is obtained and decisions can be guided towards inclusion into the UIP. Fourth, regulatory processes must be streamlined for better coordination between the Central Drugs Standard Control Organisation (CDSCO) and global agencies so that delays can be reduced and product access can be accelerated. Fifth, vaccine hesitancy should be addressed by strengthening community-level demand through frontline health worker engagement and culturally appropriate communication is essential to address vaccine hesitancy. Finally, a phased rollout prioritizing high-risk populations like preterm infants, children with congenital heart disease, and those in high-density, low-income settings is both clinically and economically justified.

CONCLUSION

RSV prevention has entered a transformative era, with multiple licensed vaccines and monoclonal antibodies demonstrating high efficacy across target populations. However, the gap between scientific achievement and public health impact remains wide, particularly in India and LMICs where the burden is greatest. This scoping review identifies four priority areas for action: (i) establishing standardised national RSV surveillance within India's IDSP; (ii) negotiating affordable access to nirsevimab and maternal vaccines through differential pricing and GAVI-supported mechanisms; (iii) integrating RSV immunisation within the UIP using existing cold chain and frontline worker infrastructure; and (iv) implementing evidence-based, community-tailored communication strategies to address vaccine hesitancy. Addressing these implementation gaps—not further vaccine development alone—will determine whether the promise of RSV prevention is realised for the populations that need it most.

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