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# Respiratory Syncytial Virus: Epidemiological Insights, Emerging Interventions and the Indian Perspective

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## ABSTRACT

Respiratory Syncytial Virus (RSV) is a major cause of acute lower respiratory tract infections (ALRTIs) in infants, young children, and the elderly, contributing significantly to global morbidity and mortality. With over 33 million ALRTI cases and more than 100,000 RSV-related deaths annually among children under five, the burden is particularly severe, in low and middle-income countries. RSV infection displays a seasonal pattern that has shifted in recent years, influenced by the COVID-19 pandemic and associated immunity gaps. The virus's pathogenesis involves complex interactions between viral proteins and the host immune system, leading to varying disease severity. Recent advances in molecular biology and immunology have driven the development of innovative vaccines and monoclonal antibodies, including those targeting the prefusion conformation of the RSV F-protein. Multiple strategies such as maternal immunization, passive antibody prophylaxis, and vaccination for older adults, have demonstrated substantial efficacy in preventing RSV-associated hospitalizations. However, disparities in access and public health infrastructure remain key challenges, particularly in India. This review provides an updated synthesis of RSV epidemiology, pathogenesis, clinical impact, current preventive and therapeutic approaches, and future directions, with particular attention to recent advancements and their relevance in the Indian healthcare context.

***Keywords:*** Respiratory Syncytial Virus (RSV), acute lower respiratory tract infections (ALRTIs), maternal immunization, monoclonal antibodies, epidemiology, India.

## INTRODUCTION

Respiratory syncytial virus (RSV) belongs to the Pneumovirinae subfamily of the Paramyxoviridae family. It has an envelope and negative-sense, single-stranded RNA. It is classified into two major serotypes, RSV-

A and RSV-B, with further genotypic variations.(1) First isolated in 1956 from chimpanzees with cold-like symptoms and initially named 'Chimpanzee coryza agent' (CCA), it was renamed the following year after being found in children with ALRTI. RSV is a major cause of acute lower respiratory tract infections (ALRTIs) in infants and young children, leading to significant global morbidity and hospitalizations. While it predominantly affects young children, RSV is now increasingly recognized as a serious pathogen in older adults and those with underlying chronic illnesses.(2).

RSV contributes to an estimated 33 million ALRTI episodes, over 3 million hospitalizations, and more than 100,000 deaths each year among children under five, with majority of deaths belonging to low and middle-income countries.(3) It is estimated to be responsible for 3.6% of all deaths among infants under six months of age globally, with the burden being disproportionately higher, again in low and middle-income countries, where access to prevention and treatment modalities, remains limited.(4) In infants under one year of age, RSV is responsible for nearly half of all severe respiratory infections, frequently necessitating hospitalization, oxygen therapy, or intensive care.(3)

Classically, RSV epidemics follow a seasonal pattern, peaking during the winter in temperate regions and during the rainy season in tropical areas. However, since the COVID-19 pandemic, significant shifts in seasonality have been observed, with off-season peaks reported in countries such as the United States and Australia, likely due to reduced exposure and immune priming, during periods of social distancing and lockdowns.(5,6) The pattern of RSV subtype circulation also varies by region and year. In Australia, biennial outbreaks typically alternate between RSV-A and RSV-B dominance, but subtype has not been strongly associated with clinical severity. A similar trend is observed in Brazil, where peak transmission aligns with the March to June rainy season. In that setting, disease severity has been linked more closely to viral load and host immune response, particularly elevated TNF-α and MMP-9, than to viral subtype.(7)

In India, RSV is one of the most common viral agents causing hospitalization for ALRTIs in infants and young children. The virus shows a clear seasonal trend, with infection rates peaking between November and February, consistent with findings from other parts of the Northern Hemisphere.(3,7) Recent studies from the region have underscored RSV's substantial role in pediatric admissions, reinforcing the need for targeted public health interventions.(4) Subtype circulation includes both RSV-A and RSV-B, but no conclusive association with disease severity has been established.(7) At a more regional level, a prospective study conducted in Chandigarh between 2013 and 2016 provides insight into RSV burden in northern India. The study focused on children aged 2 months to 5 years hospitalized with respiratory symptoms and found a seasonal peak during winter months. Among RSV-positive children, about 10% were classified as having severe ALRTI, and severity was more closely linked to underlying host factors, such as prematurity or congenital heart disease and inflammatory markers, rather than RSV subtype.(7)

Recent studies have also highlighted the resurgence of RSV cases post-COVID-19 pandemic, indicating shifting epidemiological trends.(8) In the post-COVID-19 era, disruptions in viral transmission patterns have led to what has been termed "immunity debt", a phenomenon linked to reduced early-life exposure to common respiratory viruses. This has resulted in earlier and more intense RSV outbreaks, along with an increase in nosocomial cases.(9)

The clinical manifestations range from mild upper respiratory tract symptoms to severe lower respiratory tract disease, majorly, bronchiolitis and pneumonia. While most

children with RSV recover within one to two weeks, some may need hospitalization, particularly those who were born prematurely or have pre-existing medical conditions such as chronic lung disease, congenital heart disease, and immunodeficiency. (10) Older adults and immunocompromised individuals are also at risk for severe outcomes, including exacerbations of chronic obstructive pulmonary disease (COPD) and heart failure. A study in India revealed that RSV was responsible for a significant proportion of pneumonia cases requiring ICU admission in older adults.(11) Immunosenescence in elderly patients is a critical factor leading to impaired RSV immunity and higher hospitalization rates.(2)

Diagnosis of RSV is based on clinical presentation, laboratory testing including viral detection methods. Gold standard for RSV detection is Real-time reverse transcription polymerase chain reaction (rRT-PCR), due to its high sensitivity and specificity. Other diagnostic tools include antigen-based rapid tests and viral culture, though these are less commonly used in clinical settings. Emerging multiplex PCR based platforms have demonstrated high accuracy in simultaneous detection of RSV and other respiratory viruses, improving diagnostic efficiency.(12) Recent systematic reviews have highlighted the need for maintaining PCR based surveillance due to the limited sensitivity of rapid antigen tests.(13)

**Virology and Pathogenesis**

RSV initiates infection by interacting with multiple host cell receptors. While the G-protein facilitates viral attachment, recent studies have identified nucleolin and CX3C chemokine receptor-1 (CX3CR1) as potential host receptors that enable viral entry into ciliated airway epithelial cells, suggesting that viral tropism and pathogenesis may be influenced by host receptor distribution and expression levels.(7) In addition to receptor binding, RSV entry is mediated by the F-protein, which promotes membrane fusion and the formation of syncytia, multinucleated giant cells that enhance viral spread and immune evasion. Following replication in the cytoplasm, RSV induces cytopathic effects, including epithelial cell necrosis, sloughing, and disruption of mucociliary clearance, factors central to the clinical manifestations of bronchiolitis.(14)

The immune response to RSV, although critical for viral clearance, contributes significantly to disease severity. In infants, particularly those with immature immune systems, RSV infection tends to shift the immune profile toward a Th2-skewed phenotype, with increased production of IL-4, IL-5, and IL-13, and suppression of IFN-γ responses. This Th2 dominance contributes to airway inflammation, mucus hypersecretion, and goblet cell metaplasia, hallmarks of bronchiolitis and key features of asthma pathology. Evidence also implicates increased activity of innate lymphoid cells (ILC2s) and reduced function of plasmacytoid dendritic cells and regulatory T cells in severe RSV infections. These immune patterns can result in long-term airway remodeling and hyperresponsiveness. Despite decades of research, the complex interplay of viral pathogenesis and host immunity remains incompletely understood, posing ongoing challenges for vaccine development.(15) Several epidemiological and immunological studies have shown that infants with severe RSV bronchiolitis have an increased risk of developing recurrent wheezing and asthma later in childhood, although causality remains under investigation.(16)

In addition to immune-mediated pathology, RSV exhibits a unique structural feature that plays a significant role in its transmission and spread. The virus forms filamentous structures, known as virus filaments, on the surface of infected respiratory epithelial cells. These filaments not only serve as platforms for the assembly of mature virions but also mediate localized cell-to-cell virus transmission, enhancing the efficiency of

infection within the respiratory tract. Filament formation, which occurs on lipid raft microdomains of the host cell membrane, is dependent on host cytoskeletal elements such as F-actin and GTPases like RhoA and Rac1. Disruption of filament formation significantly impairs viral spread, highlighting its importance in RSV biology and as a potential antiviral target.(6) Moreover, viral load itself may not directly determine disease severity, but when paired with elevated pro-inflammatory cytokines such as TNF-α and MMP-9, it correlates strongly with more severe disease presentations in children.(7)

## Prevention Strategies and Treatment Approaches

Effort to prevent RSV infection, is mainly vaccination including maternal vaccination which has been a revolutionary step in prevention of RSV in infants. Passive immunization in the form of monoclonal antibodies have brought a significant contribution in the management of RSV cases.

### *Vaccination in older adults*

The pathogenesis of RSV involves a strong host immune response, including proinflammatory cytokines like TNF-α and IL-6, while the viral F (fusion) protein, essential for viral entry, has emerged as a key target for vaccine development.(7) The evolving understanding of RSV pathogenesis has shaped vaccine development strategies. Past attempts, including a failed formalin-inactivated vaccine in the 1960s, highlighted the importance of inducing balanced and durable immunity without enhancing disease. Recent advances focus on targeting the prefusion conformation of the F-protein, which elicits potent neutralizing antibodies.

Three vaccines have been developed and approved of for individuals aged 60 years and above: Arexvy (GSK), Abrysvo (Pfizer), and mResvia (Moderna), especially for those at high risk of severe disease. These vaccines employ different platforms, adjuvanted protein subunit, unadjuvanted protein subunit, and mRNA technologies respectively, and have demonstrated significant efficacy in reducing RSV-associated illness and hospitalization in this vulnerable age group.(17–19) This recent approval of three RSV vaccines, marks a significant turning point in RSV prevention. One of these vaccines is also approved for maternal use to confer passive protection to infants through transplacental antibody transfer.(18)

Arexvy (GSK) is an AS01E-adjuvanted recombinant RSVPreF3 vaccine targeting RSV-A. It was evaluated in the AReSVi-006 trial, which enrolled over 24,000 older adults. In the first RSV season, Arexvy showed 82.6% efficacy against RSV-LRTD and 94.1% efficacy against severe LRTD.(17,18) Efficacy declined over time but remained notable, 56.1% and 64.2% in the second season, and 48.0% and 62.9% after three seasons for LRTD and severe LRTD, respectively.(17) Real-world studies have also shown that Arexvy attenuates symptom severity and preserves quality of life during breakthrough RSV infections.(20) However, safety signals such as Guillain–Barré Syndrome (GBS) have emerged in post-marketing surveillance, warranting continued monitoring.(18)

Abrysvo, a bivalent unadjuvanted protein subunit vaccine composed of stabilized prefusion F proteins from RSV-A and RSV-B, was assessed in the RENOIR trial. In season one, Abrysvo showed 66.7% efficacy against RSV-LRTD with two or more symptoms, and 85.7% with three or more symptoms. In season two, efficacy declined to 55.7% and 77.8%, respectively.(17,18) Immunogenicity data showed a 9.8-fold and 8.5-fold increase in neutralizing antibody titers against RSV-A and B, respectively, one month post-vaccination.(18) Abrysvo remains the only RSV vaccine approved for both older adults and pregnant women, but like Arexvy, it has been associated with a slightly higher reported rate of GBS in post-licensure monitoring.(17)

mResvia, an mRNA-based vaccine encoding RSV-A prefusion F protein, was evaluated in the ConquerRSV trial. In the first season, it demonstrated efficacy of 83.7% against RSV-LRTD (≥2 symptoms) and 86.7% against severe RSV disease.(17,18) However, protection waned over time: 62.5% at ~9 months, and 50.3% at 18 months, suggesting that booster dosing may be required in the future.(17) Importantly, no major safety concerns such as GBS or myocarditis were identified in clinical trials, and the vaccine was generally well tolerated.(18)

All three vaccines have been incorporated into ACIP's 2024 recommendations, which advise a single dose for adults ≥75 years and for those aged 60–74 years with increased risk of severe RSV disease. Routine revaccination is not yet recommended, but ongoing data from multi-season studies may influence future guidelines.(17)

Thus, Arexvy, Abrysvo, and mResvia offer significant clinical benefit in reducing the burden of RSV in older adults. While their efficacy profiles differ modestly, all have shown robust protection during the first RSV season and are instrumental in public health efforts to mitigate severe RSV outcomes. Continued surveillance, head-to-head comparisons, and studies in immunocompromised or frail subpopulations will help refine long-term strategies for RSV vaccination in this growing demographic.

### *Monoclonal Antibodies (Passive immunization)*

Monoclonal antibodies (mAbs) have become an essential tool in the prevention of RSV infection, particularly for high-risk infants such as those born prematurely or with chronic health conditions. These antibodies work by targeting the RSV fusion (F) glycoprotein, a highly conserved viral surface protein crucial for viral entry into host respiratory epithelial cells.(18)

Palivizumab was the first monoclonal antibody approved for RSV prophylaxis, licensed in 1998. It binds to antigenic site II of the F-protein and inhibits viral fusion with host cells.(3,18) Despite its efficacy in reducing RSV-related hospitalization in high-risk infants, its short half-life (~20 days) necessitates monthly intramuscular injections over five months of the RSV season. This dosing schedule, combined with high costs, limits its utility to select populations, mainly in high income settings.(3)

Nirsevimab (Beyfortus), a next-generation monoclonal antibody overcomes the limitations of palivizumab. It targets the highly conserved antigenic site Ø on the prefusion conformation of the RSV F-protein and has an extended half-life (~69 days), enabling single-dose protection throughout an entire RSV season.(18) Clinical trials such as MELODY and HARMONIE have demonstrated that nirsevimab significantly reduces RSV associated lower respiratory tract infections (LRTIs) and hospitalizations, with efficacy estimates ranging from 74% to nearly 90% depending on disease severity.(3,21,22)

Clesrovimab (also known as MK-1654) is a novel monoclonal antibody currently in Phase 3 clinical trials. It binds to antigenic site IV of the F-protein, a region with low mutation rates, and has shown promising results in early studies due to its extended half life and good penetration into nasal epithelial lining fluid, crucial for targeting initial sites of RSV infection.(3,18) Its single-dose intramuscular administration is being evaluated for safety and efficacy in both preterm and term infants, with results anticipated to support broader use in pediatric populations.(3)

Together, palivizumab, nirsevimab, and clesrovimab represent a progressive evolution in RSV immunoprophylaxis, from limited, high-risk use to broader, long-lasting protection with improved accessibility and clinical outcomes.(3,18)

### *Maternal Vaccination (Passive immunization of infant)*

Maternal vaccination represents a strategic approach to protect neonates from severe

RSV infections during the first few months of life, a period when infants are highly vulnerable and cannot mount adequate immune responses. The recent approval of the RSVpreF vaccine (Abrysvo®) for use in pregnant women offers a major advancement in RSV prevention through passive immunity.(3,23)

Abrysvo® is a bivalent subunit vaccine containing stabilized prefusion F-proteins from both RSV A and B subtypes. The prefusion form of the F protein is a key target for neutralizing antibodies and has been shown to elicit more potent immune responses compared to the postfusion conformation.(3) Abrysvo was approved in 2023 for administration to pregnant women between 32–36 weeks of gestation to protect newborns through transplacental antibody transfer. However, recent meta-analyses suggest a potential association between maternal RSV vaccination and increased odds of preterm birth, warranting further safety monitoring.(23)

In a pivotal phase III trial, Abrysvo® demonstrated 81.8% efficacy against severe RSV-associated lower respiratory tract infections (LRTIs) within the first 90 days after birth, and 69.4% efficacy at 180 days.(3,17) These results support its role in protecting infants during their most vulnerable period. Additionally, maternal and umbilical cord blood analyses confirmed robust transplacental antibody transfer, with elevated RSV neutralizing titers observed after administration of the unadjuvanted 120 µg formulation.(17) However, concerns about preterm birth emerged during clinical evaluations. Preterm delivery occurred in 5.3% of vaccine recipients vs. 2.6% of placebo recipients in the phase II trial, and in 5.7% vs. 4.7%, respectively, in the phase III trial.(17) Although these differences were not statistically conclusive, they highlight the need for continued pharmacovigilance to assess any potential causal relationship.

Maternal immunization offers a universal strategy that does not require individualized risk assessment or repeated infant dosing, as seen with monoclonal antibody prophylaxis. The success of RSVpreF reflects the progress in structure based vaccine design and the viability of maternal immunization as a scalable public health tool.(24)

The vaccine not only reduce RSV related morbidity but may also help lower the risk of chronic respiratory complications like asthma. Ongoing studies aim to determine whether preventing early RSV infection can alter the long term respiratory trajectory. Overall, maternal immunization with Abrysvo® represents a promising advancement in reducing RSV related hospitalizations and mortality in early infancy. Nonetheless, ongoing safety monitoring will be essential to ensuring its optimal and responsible implementation.

Treatment of RSV infection is primarily supportive, including oxygen therapy, hydration, and respiratory support as needed. Antiviral therapies such as ribavirin are generally reserved for immunocompromised patients due to limited efficacy and concerns over toxicity. Recent years have seen promising advances in the development of targeted antivirals, such as GS-5806 (Presatovir) and JNJ-53718678, which inhibit RSV F-protein mediated viral fusion and have demonstrated significant reductions in viral load and symptom severity in clinical trials. Other small molecule inhibitors like EDP-938, which targets the RSV N-protein to block post-replication viral processes, and ALN-RSV01, a siRNA-based therapeutic, have shown potential, in both in-vitro studies and early phase trials, though clinical effectiveness varies.(24)

Additionally, novel agents such as Shionogi's S-337395 and Enanta's Zelicapavir are in ongoing clinical evaluation, showing encouraging early results in reducing disease burden. Computational approaches have also been employed to design potential RSV vaccine candidates, emphasizing the need for further translational research and clinical validation.(25,26) Meanwhile, SCFAs are being investigated for their

immunomodulatory effects, offering a novel avenue for adjunctive therapy.(27) Overall, despite the lack of a universally approved antiviral treatment, expanding research into monoclonal antibodies, fusion inhibitors, and host-directed therapies mark an encouraging shift in RSV management strategies.

**Surveillance and Future Directions**

Global surveillance initiatives, such as the World Health Organization's Global Influenza Surveillance and Response System (GISRS), have expanded to include RSV monitoring. In March 2025, the WHO formally announced the integration of RSV and other high priority respiratory viruses into the enhanced GISRS platform, aiming to strengthen global preparedness for respiratory pathogens with epidemic or pandemic potential.(28) This expanded framework is designed to improve virus detection, sequence sharing, and coordinated response efforts by leveraging the existing network of over 160 laboratories and surveillance centers worldwide. Enhanced genomic surveillance and integration of RSV testing into respiratory disease surveillance programs are crucial for understanding viral evolution and optimizing prevention strategies. Wastewater based epidemiology has also been proposed as an innovative approach to RSV surveillance, demonstrating early detection potential.(29, 30)

**Potential Preventive Strategies for RSV in the Indian Scenario**

RSV, few years back was considered a disease of the west but lately, it has emerged as a significant health problem in India. The disease probably, was always present here but went undiagnosed because the diagnostic procedure required a molecular based test which was not readily available in pre-covid era. Covid-era brought this diagnostic modality to almost every lab. Currently, RSV is diagnosed as a routine diagnostic procedure in many labs. Also, the new management protocols with maternal immunization and monoclonal antibodies have made targeted management feasible.

In India, the seasonal burden of RSV among infants and young children highlights an urgent need for effective preventive strategies. Hospital based studies have consistently shown RSV to be a leading cause of acute lower respiratory tract infections in children under five years of age, with peak incidence observed during the winter months between November and February.(7) Despite its high prevalence and clinical impact, India currently lacks a national RSV immunization program, and preventive options remain limited to supportive public health measures.

Maternal immunization can be observed as a promising preventive strategy in the Indian context. Recent trials of RSV prefusion F-protein-based vaccines have shown encouraging results globally, with maternal vaccination reducing the risk of severe RSV infection in early infancy. However, implementation in India is still to be planned. Public perception plays a significant role in uptake; while Indian mothers and healthcare providers generally express positive attitudes toward maternal immunization, concerns around vaccine safety during pregnancy and lack of RSV awareness may hinder acceptance.(3) Addressing these concerns through culturally tailored educational initiatives and integrating RSV vaccines into existing antenatal care programs could improve coverage and public trust.

Monoclonal antibodies, particularly nirsevimab, offer another important avenue for RSV prevention in infants, especially in the high-risk group of preterm or medically vulnerable neonates. Compared to palivizumab, which requires monthly dosing and is not widely used in India due to its high cost and logistical challenges, nirsevimab provides season-long protection with a single intramuscular dose. While its introduction into the Indian healthcare system holds promise, Babawale et al. emphasize the need for careful evaluation of cost-effectiveness, procurement

mechanisms, and cold chain logistics before large-scale deployment.(3,5)

India's participation in global RSV research and policy discussions, including the 8th ReSViNET Conference held in Mumbai in 2024, reflects growing national interest in RSV control. The conference highlighted several vaccine platforms under development, such as mRNA based vaccines, bivalent F-protein formulations and vector based candidates, many of which are undergoing or preparing for clinical trials that may include Indian cohorts.(31) Strategic inclusion of RSV vaccination in India's Universal Immunization Programme (UIP), once viable candidates receive global and national approvals, would represent a major step forward in protecting Indian children against RSV.

In summary, preventive strategies in India must be guided by region-specific disease burden data, vaccine accessibility, and public health infrastructure. A combination of maternal immunization, targeted monoclonal antibody use, and robust health communication strategies could substantially reduce RSV-associated morbidity and mortality in Indian infants.

## CONCLUSION

Maternal immunization with stabilized pre-fusion F protein-based vaccines has shown promising efficacy in reducing severe RSV in neonates. Long-acting monoclonal antibodies, such as nirsevimab, now licensed for broad infant use, have demonstrated excellent real-world effectiveness in preventing RSV associated hospitalizations and oxygen requirements. The integration of these novel vaccines and monoclonal antibodies into immunization programs signals a transformative era in RSV management, with far reaching implications for public health. Despite decades of research, RSV continues to cause substantial morbidity and mortality, exacerbated by gaps in access to diagnostics, vaccines, and antiviral therapies.

India's growing involvement in RSV surveillance and clinical trials presents an opportunity to tailor public health responses through region-specific strategies. Strengthening molecular surveillance, improving awareness and vaccine acceptance, and integrating RSV interventions into existing maternal and child health programs will be essential for effective disease control. Continued investment in preventive strategies and public health implementation is therefore essential.

### *Declaration by Authors*

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