HEALTHCARE DELIVERY

The dawn of preventing respiratory syncytial virus lower respiratory tract infections in children

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Respiratory syncytial virus (RSV) is the commonest cause of lower respiratory tract infection (LRTI) in children, particularly those aged <1 year. In South Africa (SA), increased hospitalisation rates during the RSV season, including access to intensive care facilities, place a huge burden on the healthcare system. Furthermore, RSV-LRTI during early childhood may lead to long-term respiratory sequelae, including recurrent wheezing, asthma, and impairment of lung function. Recently, two new RSV prevention strategies have emerged: nirsevimab, a long-acting monoclonal antibody, and a maternal RSV vaccine. Both strategies have shown high efficacy in reducing RSV-LRTI hospitalisation in infants and are being considered for licensure in SA. Implementation of these prevention strategies, combined with public engagement and collaboration between stakeholders, could significantly reduce RSV-related morbidity and mortality in SA.

Keywords: Respiratory syncytial virus, RSV, children, pneumonia, bronchiolitis, nirsevimab, maternal vaccine.

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Globally, the leading cause of death in children 1 - 59 months of age is lower respiratory tract infections (LRTIs). They cause 18.7% (uncertainty range 15.3 - 20.2) of deaths per annum in this age group, the vast majority of which occur in Africa and South Asia.[1,2] Respiratory syncytial virus (RSV) is the commonest cause of pneumonia (20 - 40%) and bronchiolitis (40 - 80%) in children, particularly those aged <1 year.[3-7] RSV is a single-stranded RNA virus in the Pneumoviridae family, exhibiting two antigenic types, RSV A and RSV B, which vary by season and region.[8] The RSV genome encodes 11 proteins (two non-structural and nine structural), each contributing to the virus's virulence. Notably, two surface proteins serve as key targets for neutralising antibodies: the attachment (G) protein, which facilitates viral attachment to host cells, and the fusion (F) protein, which enables membrane fusion.[8] The F protein exists in two forms, pre-fusion and post-fusion. Six antigenic neutralisation sites (Ø, I - V) are present on both forms, exhibiting varying degrees of neutralising effectiveness. However, antibodies against the pre-fusion rather than the post-fusion form are most effective for preventing illness.

The global burden of RSV-LRTI in children is estimated at 3.1 million cases of LRTI hospitalisations and 120 000 deaths each year. Approximately 50% of RSV-LRTI hospitalisations and deaths in children occur in the first 6 months of life. Ninety-five percent of RSV deaths occur in low- and middle-income countries (LMICs), with ~50% in Africa.[9] Deaths from RSV are also likely to be under-reported in low-income settings, as evident from peaks in unexplained community deaths coinciding with RSV epidemics and RSV-related deaths in healthcare facilities.[10] Furthermore, the increased hospitalisation rates during RSV epidemics result in a burden on the healthcare system that impacts on the management of other illnesses, including access to intensive care facilities. Elective procedures for children with a condition such as congenital heart disease are often delayed during the RSV season because of the increased risk of severe hospital-acquired RSV disease. Most RSV-LRTI hospitalisations occur in healthy term infants in the first few months of life; however, certain subgroups, such as infants born prematurely or those with haemodynamically significant congenital heart disease, immunodeficiency, Down syndrome or chronic lung disease of prematurity, are at increased risk of severe disease. RSV-LRTI during infancy predisposes to recurrent LRTI and may lead to long-term respiratory sequelae, including recurrent wheezing, asthma, and impairment of lung function. Lung sequelae following RSV-LRTI during early childhood may persist into adulthood, resulting in long-term need for healthcare.[11] The global direct medical cost of paediatric RSV disease is estimated at USD3.1 billion annually.[9]

Current management of RSV-LRTI is largely supportive and focused on alleviating symptoms, in the absence of antiviral treatment options. Children who are hypoxic are managed with supplemental oxygen. High-flow nasal cannula oxygen has been shown to reduce the duration of hospitalisation and the need for invasive ventilation in children with moderate or severe disease.[12] Further management includes maintaining adequate hydration and avoidance of unnecessary antibiotics, steroids and nebulisation.[3]

The immediate goal to reduce the RSV burden is prevention of severe RSV-LRTI and RSV-associated hospitalisation. Until recently, prevention of RSV-LRTI has largely been non-existent in LMIC

settings, including South Africa (SA). The limited use of palivizumab, a monoclonal antibody targeting site 2 of the RSV F protein, is only recommended for children at high risk of severe RSV-LRTI. In SA, palivizumab has largely been used in the private healthcare sector because of its high cost (USD3 221 - 12 568 per course). Furthermore, because the half-life of palivizumab is only 9 - 27 days, it is logistically challenging to administer, as monthly injections are required throughout the RSV season (4 - 6 months), which may vary geographically even within a country.[9,13] Palivizumab reduces the risk of RSV hospitalisation by 51% (relative risk (RR) 0.49; 95% confidence interval (CI) 0.37 - 0.64).[14,15] The American Academy of Pediatrics has recommended administration of palivizumab during the RSV season to infants aged <12 months who are at high risk of severe disease, i.e. those born before 29 weeks' gestation, and to children aged <2 years with haemodynamically significant congenital heart disease or chronic lung disease of prematurity.[3]

In 2023, the US Food and Drug Administration and the European Medicines Agency (EMA) approved the use of a new-generation long-acting monoclonal antibody and a maternal RSV vaccine as strategies to reduce the burden of RSV-LRTI in infants, both of which are being considered for licensure in SA. Nirsevimab, a long-acting monoclonal antibody with a half-life of ~71 days, is directed against site Ø of the RSV F protein. A single dose of nirsevimab attains RSV-A and RSV-B neutralising antibody levels above the putative protective threshold for at least 6 months, consequently only necessitating a single dose for protection throughout the average RSV season. The efficacy of a single dose of Nirsevimab, 50 mg for children weighing <5 kg and 100 mg for those weighing >5 kg, was 78.4% (95% CI 51.9 - 90.3) in preventing RSV-LRTI hospitalisation in infants born at 29 - <35 weeks' gestation and 76.8% (95% CI 49.4 - 89.4) in those born at >35 weeks' gestation, through 150 days after administration.[16-19] The real-world vaccine effectiveness of nirsevimab in a matched case-control study undertaken in France, where 60 of 690 hospitalised infants with RSV bronchiolitis received nirsevimab compared with 97 of 345 non-RSV hospital visits, yielded adjusted effectiveness of 83.0% (95% CI 73.4 - 89.2) against RSV-LRTI hospitalisation.[20] Furthermore, a meta-analysis of studies conducted in the USA and three European countries over the 2023/24 RSV season yielded vaccine effectiveness of 90.5% (95% CI 87.1 - 92.9) against RSV-associated LRTI,[19] and in a 2023 - 2024 immunisation campaign in Spain in which 9 408 infants received nirsevimab, effectiveness was 82.0% (95% CI 65.6 - 90.2) against RSV-related LRTI, and notably 69.2% (95% CI 55.9 - 78.0) against all-cause LRTI hospitalisations and 66.2% (95% CI 56.0 - 73.7) against all-cause hospitalisations.[21] The current cost of nirsevimab is ~USD520 per dose for 50 mg and 100 mg doses in high-income countries, but there has been lower pricing in other countries such as Chile; tiered pricing may make it more affordable in LMICs. For SA, a dose cost of USD120 results in an incremental cost-effectiveness ratio below the country's GDP per capita.[22] Importantly, production capacity needs to meet the demand, particularly in LMICs, where the burden of disease is highest.

Maternal vaccination has been established as a key strategy for protecting pregnant women and their infants from diseases such as tetanus, pertussis, influenza and COVID-19.[23] Vaccination is typically targeted during the second or third trimester to maximise the transfer of neutralising antibodies from the mother to the fetus. This transfer occurs through an active process where maternal immunoglobulin G (IgG) antibodies bind to the Fc receptor (FcRn) on placental cells and are then transported into the fetal circulation.[23] By the third trimester, antibody levels in the baby match or exceed maternal levels. However, the efficiency of this transfer can be influenced by factors such as the specific IgG subclass, antigen specificity, and maternal characteristics such as chronic infections, advanced age, high parity, a high body mass index, uncontrolled HIV infection, and hypergammaglobulinaemia.[24,25]

The PREPARE RSV F nanoparticle vaccine (Novavax) was the first phase III maternal RSV vaccine trial. This trial included 4 636 pregnant women who received the RSV F vaccine or a placebo between 28 and 36 weeks' gestation.[26] Although the vaccine induced high levels of anti-F IgG, the study did not meet its primary endpoint and showed a vaccine efficacy of 39.4% against medically significant RSV-LRTI and 48.3% against severe hypoxaemia-associated RSV-LRTI through 90 days,[26] and the vaccine did not achieve licensure. This study was followed by evaluation of an RSV pre-fusion F-protein vaccine produced by GlaxoSmithKline, the clinical development of which was terminated following observation of higher rates of preterm births (RR 1.37; 95% CI 1.08 - 1.74) in women randomised to receive vaccine (6.8%) compared with the placebo group (4.9%).[27]

A phase III study of the bivalent pre-fusion F-protein vaccine (bRSV-preF) developed by Pfizer (Maternal Immunization Study for Safety and Efficacy (MATISSE) trial) was undertaken across 18 countries in 7 358 pregnant women at 24 - 36 weeks' gestation, including 964 (13.0%) enrolled in SA. The overall vaccine efficacy of bRSV-preF was 57.1% (95% CI 14.7 - 79.8) and 81.8% (95% CI 40.6 - 96.3) against medically attended RSV-LRTI and severe RSV-LRTI, respectively, through to 90 days after birth, with protection evident from the time of birth. Furthermore, overall vaccine efficacy of bRSV-preF was 51.3% (95% CI 29.4 - 66.8) and 69.4% (95% CI 44.3 - 84.1) against medically attended RSV-LRTI and severe RSV-LRTI, respectively, through to 180 days after birth.[28] Overall, adverse events were not statistically different between the bRSV-preF and placebo groups. In the MATISSE trial, the overall preterm birth rate was similar between the vaccine group (5.6%) and the placebo group (4.7%) (RR 1.20; 95% CI 0.98 - 1.46). Although there was no overall difference, a post-hoc analysis showed higher preterm birth rates in upper-middle-income countries among bRSV-preF vaccine recipients (7.4%) compared with placebo recipients (4.0%) (RR 1.85; $p<0.05$), while preterm rates were similar in high-income (5.0% v. 5.1%), lower-middle-income (3.1% v. 5.9%) and low-income (2.6% v. 2.5%) countries. Most preterm births were late preterm births at 35 - 36 weeks' gestation with no increase in mortality. Importantly, in both RSV efficacy trials, preterm births were not linked to the timing of vaccine administration, and occurred >30 days after vaccination, and only in specific countries. Preterm births also did not correlate with gestational age at vaccination. Differences in preterm births between vaccine and placebo groups coincided with the surge in Delta and Omicron SARS-CoV-2 variants, but the biological basis for this finding remains unexplained.

The bRSV-preF vaccine (ABRYSVO) was therefore licensed in the USA in 2023. It was indicated for vaccination of pregnant women at 32 and 36 weeks' gestation, owing to the statistically non-significant imbalance in preterm births in the bRSV-preF recipients, most of which were late preterm. In contrast, the EMA and the UK have approved the use of bRSV-preF in pregnant women at 24 - 36 weeks' gestation. In the USA, post-marketing monitoring by the Vaccine Safety Datalink (collaborative between the Centers for Disease Control and Prevention and integrated healthcare organisations) has indicated that the incidence of preterm births (4.1%) among pregnant women who received the bRSV-preF vaccine was within the expected range (3.1 - 6.1%) compared with before vaccine introduction.[29]

Important considerations regarding the bRSV-preF vaccine in pregnant women in SA include the need for data on immunogenicity and transplacental transfer of antibody in women living with

HIV (WLWH). HIV-exposed uninfected infants have lower concentrations of maternally acquired RSV neutralising antibody, in the absence of vaccination, which predisposes them to higher rates of RSV-LRTI hospitalisation compared with HIV-unexposed infants.[30,31] Maternal hypergammaglobulinaemia due to HIV can reduce the efficiency of transplacental antibody transfer. Notably, this needs to be explored in the context of women on long-term antiretroviral therapy. The immunogenicity of bRSV-preF and transplacental efficiency of transfer are currently being evaluated in WLWH in SA.

Recommendations for the RSV prevention strategy in the SA setting

Maternal RSV vaccination and administration of nirsevimab to infants or high-risk children aged <2 years would substantially reduce the burden of RSV in SA, including hospitalisations and mortality. These two highly effective preventive strategies are cost effective, but there are some anticipated challenges in the SA context (Fig. 1).

Both are currently awaiting approval from the South African Health Products Regulatory Authority, and this would be followed by recommendations by the National Immunization Technical Advisory Group for use in SA. Implementation of these strategies will largely be based on the availability of each product, and the delivery pathways in private and state-funded facilities. In principle:

- Nirsevimab should be made available to all infants (<1 year of age) and to high-risk children between 1 and 2 years of age immediately preceding and during the RSV season (high-risk children are those with haemodynamically significant congenital heart disease, chronic lung disease, HIV, inborn errors of immunity, or neurological or neuromuscular disease).
- All pregnant women are to be offered the maternal RSV vaccine. This should be year-round to limit the programmatic challenges of delivery and to provide protection in instances of seasonal variability. In unvaccinated women or preterm newborns (<37 weeks), or if the baby is born within a month of the mother receiving her RSV vaccine, nirsevimab should be provided.

In September 2024, the WHO Strategic Advisory Group of Experts (SAGE) on Immunization made the following recommendations:[32]

- all countries should introduce passive immunization for the prevention of severe RSV disease in young infants,
- The decisions to include the maternal RSV vaccinate and/or the long-acting monoclonal antibody would need to consider the cost, financing, supply, anticipated coverage and feasibility.
- a single dose of maternal RSV vaccine should be administered in the third trimester of pregnancy and post-marketing surveillance would be necessary.

For successful incorporation of the RSV maternal vaccine and nirsevimab into public health programmes, caregiver education and public engagement to create awareness of RSV disease and the efficacy of these new interventions and to address vaccine confidence are required. There also needs to be a strong collaboration between government and pharmaceutical stakeholders to facilitate access.[33] Supporting regulatory co-ordination could speed up approval procedures, especially if accompanied by technology transfer maximising similarity with the originator product. Public sector finance and procurement mechanisms, such as Gavi, the Vaccine Alliance, could play a crucial role in facilitating access and encouraging the adoption of biosimilar products in LMICs that benefit from Gavi funding; monoclonal antibodies (clesrovimab and RSM01) with similar reported efficacy and reduced costing for LMICs are currently in the vaccine development pipeline.

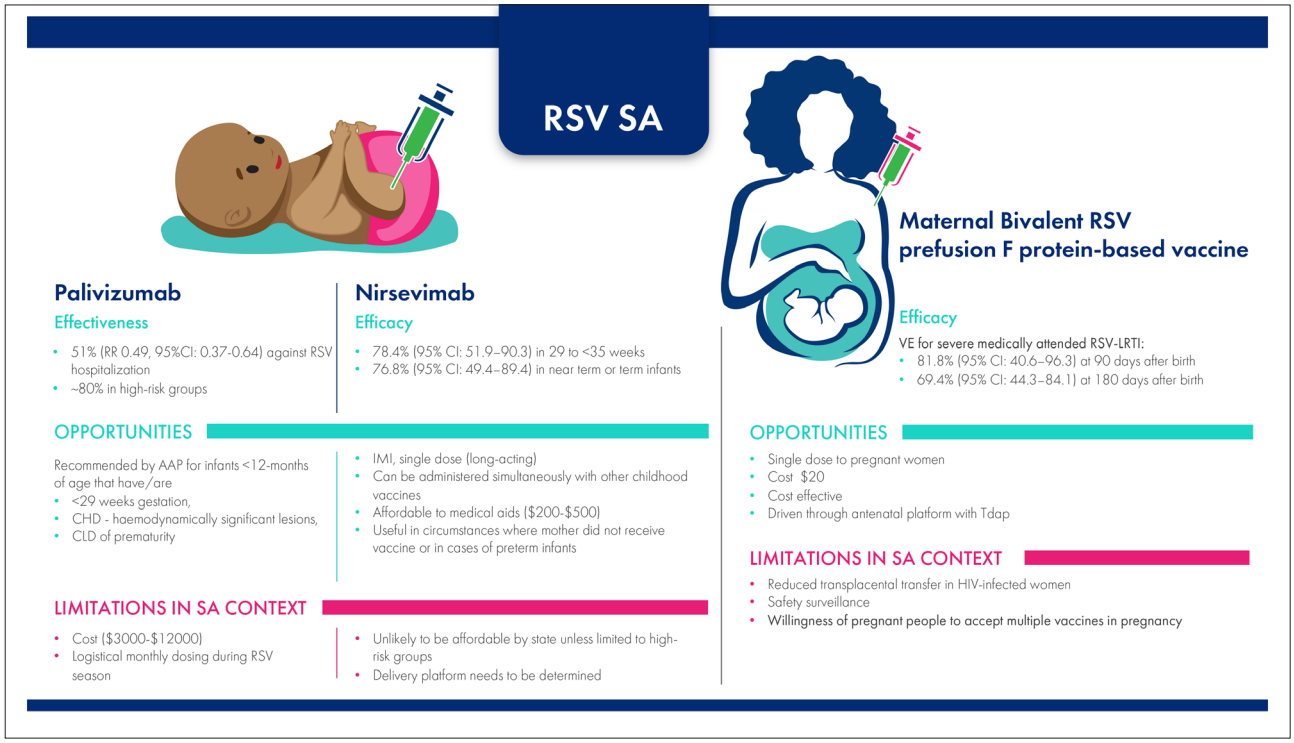

Fig. 1. Opportunities and anticipated challenges for RSV prevention strategies in an SA context. (RSV = respiratory syncytial virus; SA = South African; RR = relative risk; CI = confidence interval; AAP = American Academy of Pediatrics; CHD = congenital heart disease; CLD = chronic lung disease; IMI = intramuscular injection; VE = vaccine efficacy; LRTI = lower respiratory tract infection; Tdap = tetanus, diphtheria, acellular pertussis vaccine.)

Conclusion

RSV is now a preventable disease in infants and high-risk children, and access to these effective interventions is urgently needed for children in SA.

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Conflicts of interest. None.

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