

Joint statement for the prevention of respiratory syncytial virus in young infants in South Africa

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Respiratory syncytial virus (RSV) is the leading cause of lower respiratory tract infection and hospitalisation in young infants. The maternal RSV prefusion F protein vaccine administered to pregnant women, and the long-acting monoclonal antibody administered to infants, have been approved by regulatory authorities for prevention of RSV in infancy in South Africa (SA). This statement, supported by national pulmonology, paediatrics, obstetrics and gynaecology and infectious diseases societies, details the clinical efficacy, safety, dosing and cost-effectiveness of RSV prevention strategies relevant to SA. It also provides a practical clinical algorithm and implementation recommendations for practitioners, health system considerations, ethical counselling guidance, and a framework for surveillance and safety monitoring to optimise programme impact and equity.

Keywords. Respiratory syncytial virus, RSV, vaccination, passive immunisation, prevention, hospitalisation.

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Respiratory syncytial virus (RSV) is the leading cause of lower respiratory tract infection (LRTI) and hospitalisation in young infants worldwide and in South Africa (SA).^[1,2] Severe RSV disease in infancy results in admission to emergency departments, hospital wards and intensive care units, and is associated with later respiratory morbidity, including recurrent wheeze and an increased risk of childhood asthma.^[3] Reducing infant RSV disease is therefore a public health and economic priority.^[4-9]

Currently no antiviral treatment exists for RSV, and management of RSV LRTI is therefore largely supportive to alleviate symptoms. The immediate goal is to reduce RSV LRTI hospitalisation and severe RSV LRTI through preventive strategies. In September

2024, the World Health Organization (WHO)'s Strategic Advisory Group of Experts on Immunization (SAGE) recommended that countries implement passive immunisation strategies to prevent severe RSV disease in infants – either a long-acting monoclonal antibody (nirsevimab, clesrovimab) administered in early infancy, and to older high-risk infants (6 - 24 months) prior to and during the RSV season, or a bivalent RSV prefusion F protein maternal vaccine (RSVpreF) administered to pregnant women.^[10] Both prevention strategies have demonstrated strong efficacy and effectiveness in reducing medically attended and severe RSV LRTI in infants, associated mortality, and reducing hospitalisation for all-cause LRTI.

The purpose of this statement, targeted at paediatricians, family physicians and obstetricians, is to guide the use of RSV prevention strategies in SA. As at February 2026, the South African Health Products Regulatory Authority (SAHPRA) had approved both the RSVpreF maternal vaccine for use in pregnant women from 28 to 36 weeks' gestation, and nirsevimab single-dose, long-acting monoclonal antibody for newborns and young infants. Clesrovimab has not yet been registered for use in SA.

Overview of efficacy and safety of RSV prevention strategies

Maternal RSV vaccine

The maternal vaccine is a recombinant RSVpreF vaccine developed to contain antigens of the prefusion configuration of the F protein. This bivalent vaccine contains stabilised preF antigens against both antigenic subgroups, RSV-A and RSV-B. Once administered, the immune response includes neutralising antibodies against the preF antigens, which prevent viral penetration and fusion of RSV into host cells. The process of passive immunisation in infants occurs through transplacental transfer of maternally derived IgG from mother to fetus during pregnancy (Fig. 1).

The RSVpreF vaccine demonstrated efficacy of 81.8% (95% confidence interval (CI) 40.6 - 96.3) against severe RSV-associated LRTIs through 90 days of life and 69.4% (95% CI 44.3 - 84.1) through to 180 days in the phase 3 MATISSE trial.^[11] The real-world effectiveness was consistent with what was seen in the clinical trial. Data from Argentina showed reductions of 78.6% (95% CI 62.1 - 87.9) in RSV-associated hospitalisations among infants aged <3 months and 71.3% (95% CI 53.3 - 82.3) among those aged <6 months.^[12] A UK study showed that the adjusted effectiveness of maternal RSVpreF vaccination in preventing infant hospitalisation was 72% (95% CI 48 - 85) for infants whose mothers were vaccinated >14 days before delivery, and 58% (95% CI 28 - 75) for infants whose mothers were vaccinated at any time before delivery.^[13]

Clinical studies^[11,14,15] have not shown any evidence of increased congenital anomalies or fetal deaths linked to the vaccine. In the phase 3 MATISSE trial,^[11] a numerical imbalance in preterm birth (<37 weeks' gestation) was observed overall (5.7% v. 4.7%), although this did not reach statistical significance. However, a statistically significant increase was observed at the SA study sites (8.3% v. 4.0%, relative risk 2.06, 95% CI 1.21 - 3.51).^[16] Definitive causes between vaccination and preterm birth were not identified. Subsequent benefit-risk analyses suggested that the prevention of severe RSV disease and infant hospitalisation would outweigh potential harms associated with preterm birth, particularly when vaccination is administered later in

the third trimester and in high-burden settings.^[17] In response to this, the WHO SAGE and Global Advisory Committee on Vaccine Safety have highlighted the need for region-specific post-introduction surveillance.^[18] A multi-country study in four African countries, including SA, is currently being undertaken to evaluate maternal RSV vaccination efficacy and safety, with preterm birth and low birth weight as key outcomes (NCT06955728).

Infant monoclonal antibodies

RSV prevention with monoclonal antibodies such as palivizumab has been around since 1998.^[19] The high cost and logistical challenges of monthly dosing throughout the RSV season led to the American Academy of Pediatrics recommending its use for high-risk infants aged <12 months rather than for all infants.^[20] Recent developments of extending the half-life of monoclonal antibodies throughYTE mutations of the Fc component of IgG have favoured the introduction of two new single-dose long-acting monoclonal antibodies, namely nirsevimab, which is targeted against site Ø of the F protein, and clesrovimab, targeted against site IV.

The MELODY trial demonstrated that the efficacy of a single dose of nirsevimab through to 150 days after administration 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 infants born at >35 weeks' gestation.^[21-23] Efficacy was higher in infants aged <3 months (89.6%, 95% CI 73.8 - 96.8) and during the RSV season (83.0%, 95% CI 67.3 - 91.9). Similarly, the CLEVER trial found a single dose of clesrovimab to have an efficacy through to 150 days of 84.2% (95% CI 66.6 - 92.6) in preventing RSV LRTI hospitalisation in preterm infants born at ≥29 weeks' gestation or full-term infants, with similar efficacy through to 180 days.^[24] Vaccine efficacy (VE) has also been demonstrated against all-cause LRTI hospitalisation for nirsevimab (42.8%, 95% CI -15.8 - 71.7) and clesrovimab (VE 49.0%, 95% CI 26.7 - 64.5).^[23,24] The long-acting monoclonals also have a favourable safety profile, and no serious adverse events were reported in the CLEVER or MELODY trials.^[22,24]

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.^[25] In Chile, where a national nirsevimab strategy has been implemented, the effectiveness in preventing RSV LRTI hospitalisations was 76.4% (95% CI 72.6 - 79.7).^[26] Notably, in Chile, the number needed to immunise to prevent one RSV-related LRTI hospitalisation was 35. Nirsevimab administered to 1 083 Spanish infants after birth showed an effectiveness for preventing hospitalisation for RSV LRTI of 88.7% (95% CI 69.6 - 95.8), and similar figures for preventing emergency

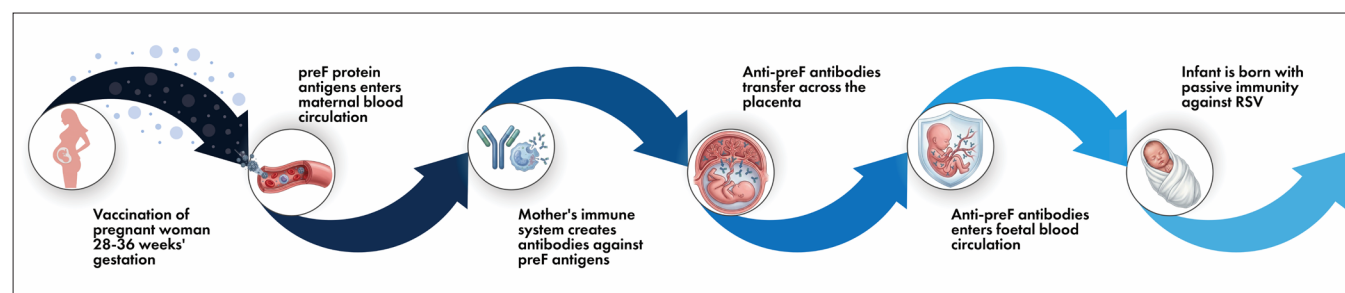


Fig. 1. Maternal vaccination and passive immunity in infants (adapted from Patel et al.^[60]). (preF = prefusion F; RSV = respiratory syncytial virus.)

room consultation (87.9%, 95% CI 70.3 - 95.1) and paediatric intensive care unit (PICU) admissions (85.9%, 95% CI 13.2 - 97.7). In addition, PICU admissions for RSV bronchiolitis declined from 9.0 (95% CI 8.6 - 9.5) per 1 000 admissions to 4.3 (95% CI 3.2 - 6.1) when comparing the pre- and post-nirsevimab periods.^[27,28] In a 2023/24 immunisation campaign in Spain in which 9 408 infants received nirsevimab, effectiveness was demonstrated against all-cause LRTI hospitalisations (69.2%, 95% CI 55.9 - 78.0) and against all-cause hospitalisations (66.2%, 95% CI 56.0 - 73.7).^[29] In Chile, effectiveness against all-cause LRTI hospitalisations was 66.5% (95% CI 61.9 - 70.5) and against all-cause hospitalisations was 47.9% (95% CI 44.4 - 51.2).^[26]

Real-world data from many high-income countries where nirsevimab has been used at scale show large and immediate reductions in RSV-related emergency visits, hospital admissions and PICU admissions.^[26-35] These real-world impacts translate directly into preserved hospital capacity for other paediatric conditions, less strain on hospital staff, greater ward and ICU bed capacity, and less emotional burden on parents and families.^[36-38]

Health economic impacts of prevention strategies

The clinical and economic burden of medically attended RSV LRTI is substantial, leading to significant morbidity, healthcare utilisation, and financial strain on health systems worldwide. Houde *et al.*^[38] showed that among the 3.7 million US infants aged <12 months each year, a total of 592 700 cases of RSV LRTI (hospitalisations $n=48\,499$, emergency department visits $n=144\,599$, outpatient clinic visits $n=399\,602$) were projected to occur, yielding total annual costs of USD1.6 billion. This annual burden among US infants is especially high for those aged <3 months, who account for 43% of total costs.

Zhang *et al.*^[6] showed that the global cost of inpatient and outpatient RSV LRTI management in young children in 2017 was estimated at ~EUR4.82 billion (95% CI 3.47 - 7.93), with 65% of these cases in low-to middle-income countries and hospitalisation accounting for 55% of global costs. They demonstrated that RSV imposed a substantial economic burden on health systems, governments and society.

Li *et al.*^[39] evaluated seven preventive strategies and the impact of these on cost and quality-adjusted life years from a healthcare payers' perspective. Both maternal vaccination and monoclonal antibody strategies can be cost-effective, depending on pricing. The combined strategy is optimal only when product costs are low. Cost-effectiveness is strongly influenced by RSV hospital burden in the target population.

SA data show that RSV has a substantial economic burden. A national costing study estimated the mean annual cost of RSV-associated illness in children aged <5 years at USD137.2 million, of which 76% was borne by the healthcare system.^[40] The costs were highest for the youngest infants (aged 0 - 2 months) at USD921.66 per episode, compared with USD623.59 for infants aged 3 - 5 months, USD583.71 for infants aged 6 - 8 months, USD716.68 for infants aged 9 - 11 months, and USD591.44 for children aged 1 - 4 years. This economic burden further supports interventions that protect infants from birth, such as maternal vaccination or long-acting monoclonal antibodies.^[40]

Cost-effectiveness modelling using SA age-specific burden and cost data suggests that RSV prevention could be economically favourable. Maternal RSV vaccination in SA was estimated to reduce

RSV-associated hospitalisations by 24.2% and deaths by 27.4%, while long-acting monoclonal antibody use was estimated to reduce hospitalisations by 33.4% and deaths by 37.9%.^[41] Although significant research has been done locally, the current cost of the product has not allowed access across all sectors in SA.

Comparing the maternal vaccine and passive immunisation

There are no high-quality studies comparing the two interventions. A French national population-based cohort study compared infant nirsevimab immunisation with maternal RSVpreF vaccination in preventing RSV-related hospitalisation in infants.^[42] The study found that, under real-world conditions and when evaluated within the same population and during the same epidemic period, passive immunisation with nirsevimab had a lower risk of hospitalisation for RSV-associated LRTI (adjusted hazard ratio (HR) 0.74, 95% CI 0.61 - 0.88). Compared with the RSVpreF vaccine, passive infant immunisation with nirsevimab had a lower risk of hospitalisation for RSV-associated LRTI than the maternal vaccine for severe outcomes, including PICU admission (adjusted HR 0.58, 95% CI 0.42 - 0.80), requiring ventilator support (adjusted HR 0.57, 95% CI 0.40 - 0.81), or requiring oxygen therapy (adjusted HR 0.56, 95% CI 0.38 - 0.81). Limitations include the fact that the study was an observational study limited to a single RSV season, precluding assessment of the durability of protection.

Health system and implementation considerations

Maternal vaccine

Antenatal care attendance patterns

Optimal antenatal care (ANC) is necessary for successful maternal RSV vaccination implementation. SA has adopted the WHO recommendations through the Basic Antenatal Care (BANC) policy, and essential ANC services are offered at no cost in public health facilities.^[43] Pregnant women should attend their first ANC visit before 14 weeks' gestation, but data from 2020 describe only 68.3% of women in SA attending their first ANC visit on time, and this was a decline from the 69.7% recorded in 2019.^[44] Since RSV vaccination is administered in the third trimester and requires only a single dose, coverage can be expected to be good if it is available. The latest data from the USA reported coverage of 41.6%,^[45] while England achieved national coverage exceeding 60% within the first year of programme roll-out.^[46] In the BERNI effectiveness study in Argentina, maternal RSV vaccination was documented in ~45 - 50% of control infants' mothers, consistent with substantial national uptake during the first season.^[47]

An SA study showed that coverage of at least one dose of maternal tetanus toxoid during pregnancy was high, which bodes well for a single-dose maternal vaccine.^[48] Problems with availability, affordability and accessibility of healthcare services have been identified as risk factors for late ANC presentation. Challenges such as transportation difficulties, distance to clinics and facility conditions further impede the initiation of ANC.

The maternal RSV vaccine needs to be delivered in a defined gestational window, so late ANC initiation (and fewer visits late in pregnancy) increases the risk of missing the eligible window and requires 'catch-up' workflows (e.g. vaccinate at the first contact once eligible, strong appointment recall, and documentation checks at every visit).^[49]

Integration into ANC platforms

The maternal case record booklet will need to be amended to clearly document RSV and Tdap (tetanus, diphtheria, pertussis) vaccination. The operational approach includes adding a single RSV vaccine status check to every ANC visit checklist once the pregnancy reaches the eligible gestational age. ANC registers and electronic tools (where available) should generate defaulter lists and appointment reminders for women approaching the dosing window. It is important that any system is able to link maternal vaccination information to infants in the first few months of life.

Long-acting monoclonal antibody

Integration into postnatal and immunisation services

SA's standard child health contact points create natural 'catch-up' opportunities for the administration of nirsevimab from birth. The Road to Health booklet schedules early return visits (e.g. 3 - 6 days after birth, then 6 weeks and onwards) and includes an immunisation section used nationally.

The operational approach includes administration at the birth facility before discharge, with documentation in the child record. The dose of nirsevimab will need to be recorded. Alternatively, if the vaccine is not given at birth, healthcare workers may use the 3 - 6-day or 6-week contact as a defined 'catch-up checkpoint', combined with a rule: 'Check eligibility at every visit during RSV season/first months of life.'

Training needs for healthcare workers

Training should be short, practical, and aligned with known missed opportunities for vaccination drivers such as stock-outs, record checking and workflow gaps. Training must include knowledge of eligibility-gestational age window for maternal vaccine (from 28 weeks' gestation), seasonality rules, catch-up logic and referral pathways for nirsevimab. Reinforcement of correct storage and handling using existing Expanded Programme on Immunisation norms and facility standard operating procedures is required. The Road to Health booklet user guidance includes vaccine handling principles (e.g. temperature control and handling of reconstituted vaccines), and must be emphasised. Training must also include accurate recording (product, batch, date, site), recognition/reporting of adverse events following immunisation (AEFI), and how to counsel caregivers on expected reactions and when to return. Healthcare workers must reinforce record checking at ANC and well-baby clinics, as 'every contact counts'.

Implementation considerations

The use of RSV prevention is recommended for all infants, as >80% of RSV LRTI hospitalisation occurs in well-nourished term infants with no risk factors.^[7-9,42,50,51] Both preventive strategies are safe and highly effective in reducing the burden of RSV and all-cause LRTI. Currently these strategies have not been rolled out in the state sector of SA but are available to the private sector at a cost of ZAR3 372.00 for the maternal RSVpreF vaccine and ZAR6 403.20 for nirsevimab.^[52,53] Notably, to date, uptake of past maternal vaccines has been low in the private sector of SA. Efforts to promote maternal vaccination should continue. Local evidence shows knowledge gaps regarding which vaccines are offered in pregnancy and childhood, and their benefits.^[49]

In April 2025, the SA National Advisory Group on Immunisation (NAGI) made a recommendation to the Minister of Health that the maternal vaccine be made available year-round to all pregnant women from 28 weeks' gestation (Fig. 2), and this was in the context of uncertainties regarding the availability and affordability of nirsevimab.^[54] Importantly, the recommendation includes co-administration of RSVpreF vaccine with other vaccines in the maternal immunisation programme, including influenza (which is given seasonally), and that the Tdap and RSV vaccines should preferably be spaced 2 weeks apart but can be co-administered if the patient presents late in pregnancy. Where possible, administer vaccines in different arms or at different injection sites.

A technical working group for RSV monoclonal antibody has been established and will make recommendations to the NAGI and the National Essential Medicines List Committee. In anticipation of the recommendations, this group will need to consider the safety, efficacy and cost-effectiveness of RSV monoclonal antibody preventive strategies for SA.

Some of the considerations are whether the monoclonal antibody would be:

- the preferred strategy for RSV prevention
- an alternative strategy for RSV prevention (alternative to the maternal vaccine)
- a targeted and complementary strategy for:
 - infants whose mothers were not vaccinated
 - infants whose mothers did not receive the vaccine timeously (<2 weeks before delivery)
 - high-risk infants (severe prematurity, hemodynamically significant congenital heart disease, chronic lung disease, HIV, inborn errors of immunity, secondary immune deficiency, or neurological or neuromuscular disease) aged 6 - 24 months at the beginning of and during the RSV season (February to May).

Two possible implementation strategies for nirsevimab should be considered:

- Pre-season immunisation of all children aged <12 months ahead of the RSV season (mass immunisation) and vaccination of all babies born during the season (Fig. 3).
- Routine immunisation of all babies at birth. Start immunisation in August/September and continue until the end of May. Half of RSV hospitalisations occur in infants born before the season, and these infants therefore need protection going into the season.^[55,56] In SA this is February to May, as mentioned above, but may need to be adjusted owing to seasonal changes.
- Immunisation of high-risk children between 1 and 2 years of age should occur immediately preceding the season.
- High-risk children include:
 - haemodynamically significant congenital heart disease
 - chronic lung disease
 - HIV
 - inborn errors of immunity
 - secondary immune deficiency, e.g. children on immunosuppressive therapy after transplantation or on chemotherapy
 - neurological or neuromuscular disease.

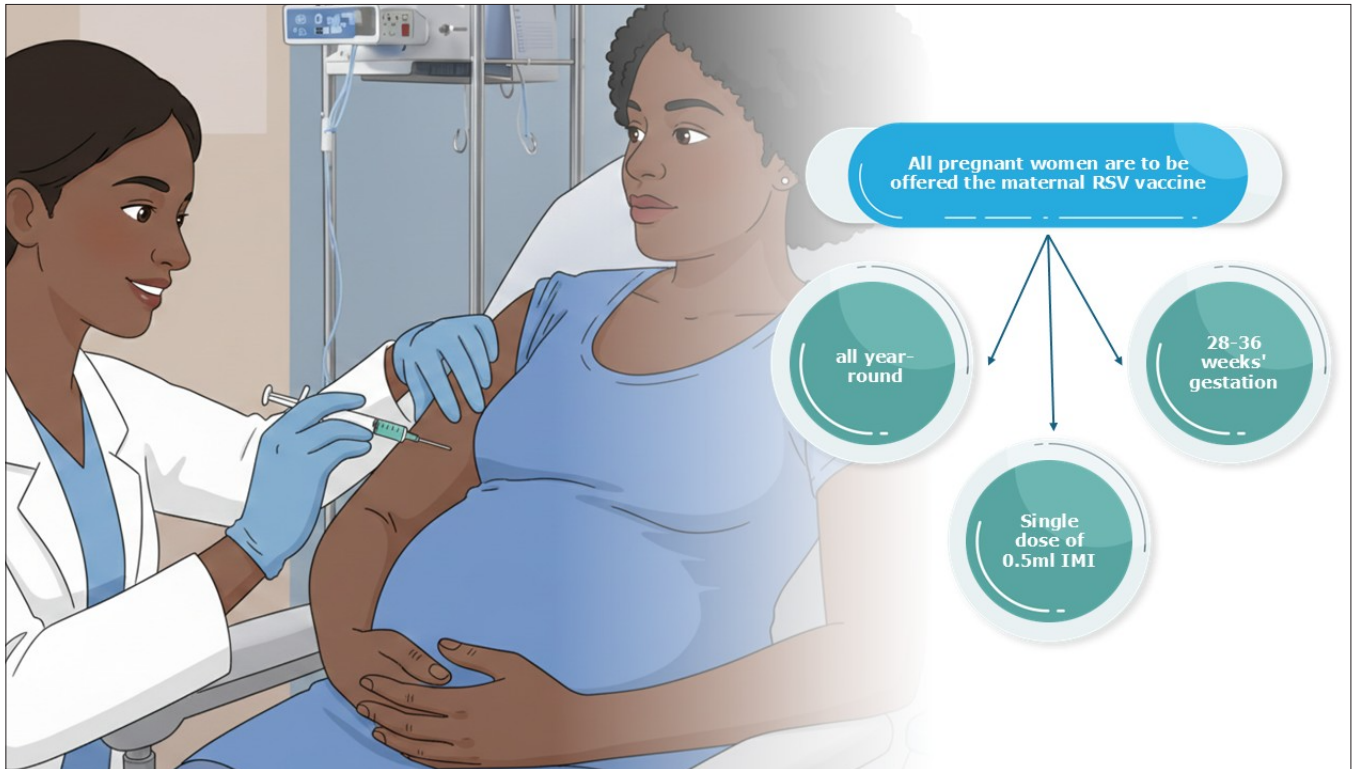


Fig. 2. Recommendations for maternal vaccination with the RSV prefusion F protein vaccine in South Africa. (RSV = respiratory syncytial virus; IMI = intramuscular injection.)

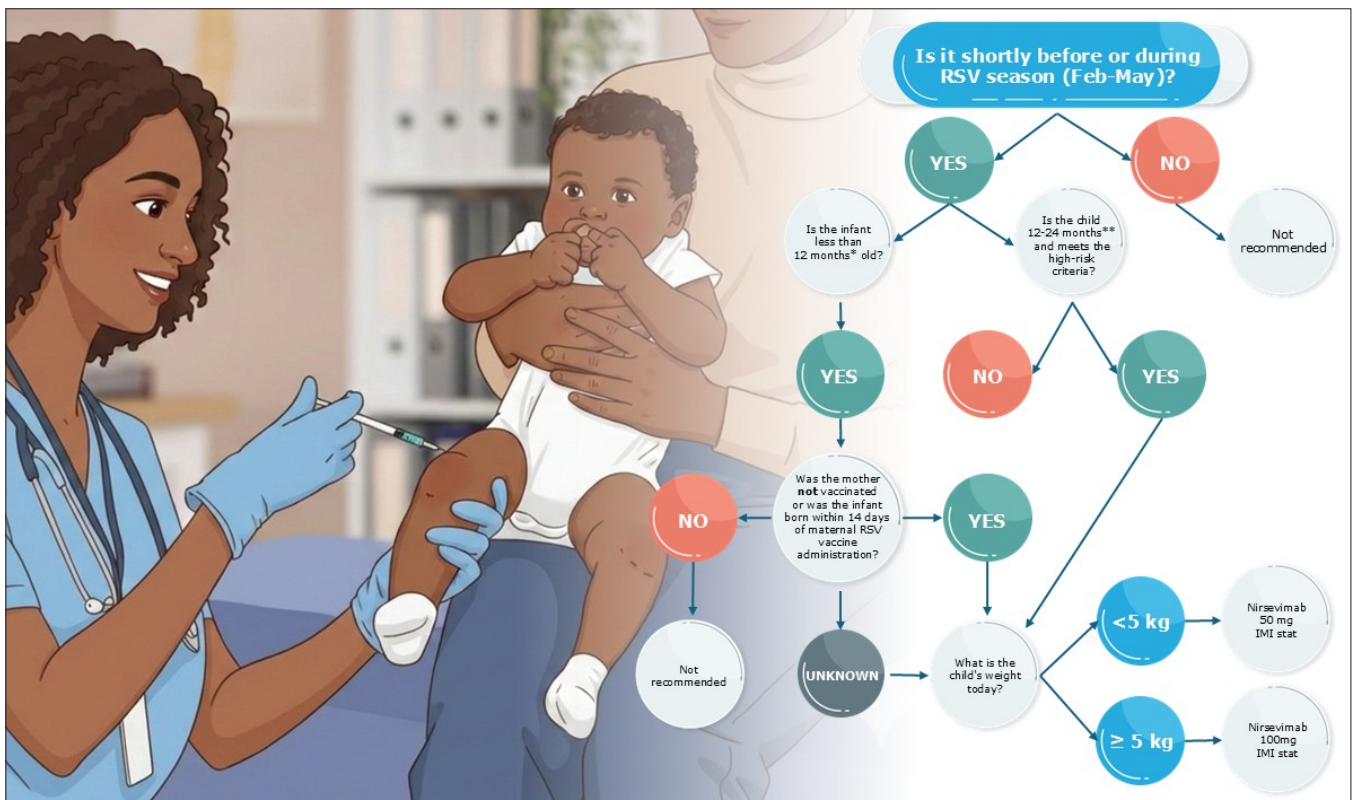


Fig. 3. Proposed recommendation for administration of long-acting monoclonal antibody for infants in South Africa. (RSV = respiratory syncytial virus; IMI = intramuscular injection; SAHPRA = South African Health Products Regulatory Authority; *Approved up to 12 months of age. Nirsevimab must at least be administered to infants <6 months of age; **SAHPRA approval pending at the time of publication of this article for infants aged 12 - 24 months.)

Monitoring, surveillance and future directions

RSV disease surveillance

In SA, surveillance for RSV is undertaken at grant-funded sentinel hospital sites, and more broadly through the National Institute of Communicable Diseases (NICD) Centre for Respiratory Diseases and severe acute respiratory illness (SARI) programmes. There are also alerts through NICD weekly respiratory pathogens surveillance reporting and NICD RSV season alerts to clinicians.^[57]

In addition, we propose a weekly ‘RSV dashboard’ which would include RSV positivity (polymerase chain reaction) in sentinel sites (influenza-like illness/SARI/pneumonia surveillance), paediatric admissions/oxygen/intensive care unit signals, and province-level trend maps for operational decisions (distribution, ‘catch-up weeks’). Furthermore, we need to monitor whether the RSV burden shifts after introduction (e.g. age distribution, severity, geographical spread) and detect unusual seasons/subtype changes (e.g. RSV-A v. RSV-B). Throughout the world, RSV product monitoring was added onto existing respiratory disease surveillance and immunisation safety systems, together with added targeted post-introduction effectiveness studies and coverage monitoring.^[58]

Safety monitoring

Safety monitoring for both products is essential. Maternal vaccination requires pregnancy-specific safety vigilance, and infant monoclonal antibody needs monitoring for adverse events. Pregnancy-specific monitoring includes documenting preterm birth, hypertensive disorders, stillbirth, neonatal outcomes (use routine maternity registers and District Health Information System where possible). Infant monoclonal antibody monitoring (nirsevimab) includes looking for hypersensitivity reactions, medication errors (wrong dose/age/weight band) and documentation completeness (batch/lot). SA already has the SAHPRA Vaccine Safety Surveillance guidance/manual, which includes procedures for AEFI surveillance/response. SAHPRA also has broader health products vigilance channels such as pharmacovigilance reporting.

Conclusion

RSV is a leading cause of hospitalisation in SA. Real-world evidence has demonstrated significant effectiveness against hospitalisation with both RSV prevention regimens.^[59] The maternal vaccine and long-acting monoclonal antibody are effective, safe products used to prevent infection and decrease the public health burden of RSV, and are therefore strongly recommended in the SA context.

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