Immunisation
Foundation of Australia

BEST PRACTICE INFANT RSV IMMUNISATION

A consensus statement to optimise protection of Australian infants through a nationally coordinated dual immunisation program.

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EXECUTIVE SUMMARY

Australia's infant respiratory syncytial virus (RSV) immunisation program requires national funding, consistent and clear eligibility criteria, and the inclusion of direct infant antibody RSV protection on the National Immunisation Program (NIP) to deliver on its full potential.

The RSV Mother and Infant Protection Program (RSV-MIPP), launched in 2025, pairs maternal vaccination with direct infant antibody protection. These complementary immunisation approaches have the potential to prevent thousands of infants from being admitted to Australian hospitals and intensive care units each year.[1]

However, split funding across state, territory, and federal jurisdictions has led to fragmented delivery, inconsistent eligibility criteria, inequitable access, and suboptimal protection of infants against severe RSV.

This consensus statement advocates for best-practice infant RSV protection and calls on policymakers to:

- Affirm the dual program model, positioning maternal vaccination and direct infant immunisation as complementary, rather than competing strategies.
- Integrate maternal RSV vaccination from 28 weeks of gestation into routine antenatal care.
- Bolster access to direct infant RSV immunisation via birth-dose delivery and catch-up pathways, including for all high-risk infants.
- Standardise eligibility, communication, and provider workflows nationally to ensure all healthcare professionals and families can give infants optimal RSV protection, regardless of location.

Australia can radically reduce the number of infants impacted by severe RSV, provided the right intervention reaches the right infant at the right time. Without improved national coordination, fragmented delivery will continue to cause confusion and preventable infant hospitalisations.

PURPOSE AND SCOPE

Developed by clinical experts, researchers, and patient advocates, this consensus statement presents evidence-based, best-practice guidance to optimise infant RSV protection in Australia. This may not reflect current federal, state, or territory guidance and funding arrangements.

Importantly, it advocates for a nationally consistent framework and eligibility criteria for maternal vaccination and direct infant antibody protection as complementary RSV immunisation strategies.

The statement is intended for immunisation providers, health services, and policymakers to:

- Support best-practice decision-making;
- Promote equitable access and outcomes across Australia; and
- Inform a coordinated national approach to infant RSV immunisation aligned with evolving evidence and implementation needs.

BACKGROUND AND RATIONALE

RSV burden in Australian infants

RSV is a leading cause of lower respiratory tract infections and hospitalisations in Australian infants, contributing to significant health system pressure.[2] This is most pronounced during the RSV season, which occurs from April to September in southern temperate regions of Australia, and more commonly in the wet season from November to April in the tropical north.[3,4]

Infants are most at risk of severe RSV in the initial months of life, but serious illness remains a threat up to two years of age – especially in high-risk groups such as preterm and low birth weight infants, those that are immunocompromised or have heart, lung, neurological, and specific genetic conditions, as well as Aboriginal and Torres Strait Islander children.[3]

By two years of age, almost all children will have been infected with RSV, and prior to the introduction of the RSV-MIPP, around 12,000 children aged under 12 months were admitted to hospital annually with RSV-related bronchiolitis or pneumonia.[2]

Severe RSV in infants may also result in long-term respiratory complications, such as a susceptibility to chest infections, as well as recurrent wheeze and asthma.[5]

The changing landscape of infant RSV protection

Until recently, options to protect against RSV were limited to palivizumab, a short-acting monoclonal antibody requiring monthly dosing and limited, largely due to its cost, to infants at high risk of severe disease.[6,7] Given its restricted use, palivizumab had limited population-level impact.

Recent scientific advances led to the introduction of two highly effective and complementary interventions:

- Maternal vaccination (Abrysvo®), administered during pregnancy to provide passive protection against severe RSV to newborns through the first six months of life.[8]
- Direct infant monoclonal antibody protection, providing protection from severe RSV for at least six months (nirsevimab, brand name Beyfortus®) and five months (clesrovimab, brand name Enflonsia®) respectively.[9-11]

In 2024, Western Australia, Queensland, the Northern Territory, and New South Wales launched state-funded infant RSV immunisation programs with a monoclonal antibody. Eligibility varied by jurisdiction, with some offering universal programs and others prioritising high-risk infants.

Real-world evidence from these jurisdictions shows substantial reductions in hospitalisations, with Western Australia reporting roughly half of the expected admissions for severe RSV compared with previous seasons.[12]

In 2025, the Australian Government introduced the dual immunisation RSV-MIPP, aiming to prevent up to 10,000 infant hospitalisations each year. Funding for the RSV-MIPP was split between the Commonwealth, state and territory governments.[1]

One component of the RSV-MIPP is the maternal RSV vaccine, which is now available to all pregnant women, year-round and at no cost, from 28 weeks of gestation through the NIP.

The parallel component of the RSV-MIPP is direct infant antibody immunisation, which is funded and delivered through state and territory programs. This has led to variations in access, eligibility, and implementation.

Now in the second year of the RSV-MIPP and informed by a rapidly evolving evidence base, there is a clear need for nationally coherent guidance on how these two immunisations work in tandem to protect Australian infants against severe RSV.

PROTECTION THROUGH A DUAL APPROACH: COMPLEMENTARY, NOT COMPETING

Australia's national aspirational coverage target of 95% for childhood immunisation[13] provides a useful benchmark for the RSV-MIPP.

In order to maximise coverage, maternal vaccination and direct infant immunisation must be positioned and promoted as complementary strategies. Together, they increase the likelihood that all Australian infants are protected against severe RSV despite the potential for missed antenatal or postnatal care, contraindications, or health system gaps.

Equity and choice must also be central to the program's design. Current jurisdictional variations risk exacerbating disparities and inequities, supporting the need for greater national consistency.

Recommended role of maternal immunisation

Available through the NIP since early 2025, maternal immunisation provides the first opportunity for RSV protection, covering infants from birth through the first six months of life.

Evidence from clinical trials and real-world implementation confirms that maternal vaccination cuts RSV-related hospitalisations, rates of severe lower respiratory tract infections,[14,15] paediatric intensive care unit (ICU) admissions, and the need for mechanical ventilation among young infants.[16,17]

The vaccine should be offered to all pregnant women, including those with comorbidities, suppressed immune systems, and complex pregnancies. The only contraindication is a previous severe allergic reaction to the vaccine.

Integrating the delivery of maternal RSV immunisation into existing antenatal care pathways, such as influenza and pertussis vaccination programs, is key to improving uptake of all three vaccinations.

Recommended role of direct infant antibody protection

Monoclonal antibodies provide an important RSV immunisation pathway, providing immediate and timely protection for newborns and older babies.

Clinical studies add to a growing body of real-world evidence that shows a high level of protection against severe RSV-related lower respiratory tract infections, which has the benefit of significant reductions in hospitalisations and ICU admissions in infants up to two years of age.[14,18,19]

Australian research indicates that one infant is saved from being hospitalised for an RSV-related lower respiratory tract infection for every 25 immunised with infant antibody protection, a rate similar to the NIP-funded rotavirus vaccine.[20]

Birth is a critical opportunity for the administration of direct infant antibody protection, with 'birth dose' delivery prior to discharge considered an effective strategy. Infant antibody protection provides immediate protection and flexibility for 'catch-up' dosing ahead of the RSV season, as well as second-season protection in selected high-risk children.

Although there is a high level of acceptance for maternal vaccination, a proportion of mothers may decline for personal reasons, including vaccine hesitancy or needle phobia. Equally, some parents prefer maternal vaccination so that their newborn does not receive an injection in the first days of life. Both preferences should be honoured and can be accommodated under a dual program.

Baby Jimmy. Lives with cystic fibrosis and hospitalised for a week with severe RSV.

TABLE 1

ADDITIONAL RISK FACTORS FOR SEVERE RSV DISEASE IN INFANTS

- Being of Aboriginal and Torres Strait Islander descent^
- Preterm birth before 36 weeks gestational age^
- Having a haemodynamically significant congenital cardiac disease
- Significant immunosuppression, such as:
  - Malignancy
  - Solid organ transplant
  - Haematopoietic stem cell transplant
  - Inborn errors of immunity associated with T cell or combined immunodeficiency, such as severe combined immunodeficiency (SCID)
- Chronic respiratory disease, including:
  - Chronic lung disease requiring ongoing oxygen or respiratory support
  - Cystic fibrosis with severe lung disease or weight for length under the 10th percentile
- Neurological conditions where the infant may need respiratory support, or their lungs were impaired
- Chromosomal abnormalities such as Trisomy 21 or other genetic conditions that increase the risk of severe RSV

^ Recommended revisions to the Australian Immunisation Handbook – risk factors for severe RSV disease in infants and young children.[21]

Baby Zach. Airlifted to intensive care and hospitalised for 15 days with severe RSV.

Infants entering their first RSV season should receive infant antibody protection at birth or up to eight months of age if:

- Their mother did not receive maternal immunisation at least two weeks before birth;
- They were born to mothers who are immunosuppressed; and/or
- They have additional risk factors for severe RSV disease (refer Table 1)

Children aged between eight and 24 months and at risk of severe RSV are also recommended to receive infant antibody protection before their second RSV season. This is in recognition that the burden of RSV, although lower than in younger infants, persists into the second year of life – particularly for higher risk children. At the time of publication, nirsevimab is the only monoclonal antibody registered in Australia for second-season use.

Aboriginal and Torres Strait Islander infants face a disproportionate burden of severe RSV, compounded by higher rates of preterm birth, reduced access to antenatal care, and healthcare workforce constraints that limit the reliability of catch-up dosing. For these infants, access to infant antibody protection during their first RSV season is recommended as a second layer of protection when maternal antibodies have waned.

Second-season RSV protection for Aboriginal and Torres Strait Islander infants should be provided Australia-wide, but this approach is currently only funded in some states and territories.

The eligibility criteria for preterm infants should also be widened from those born at less than 32 weeks of gestation to those born at less than 36 weeks. Studies show that although infants born at less than 32 weeks have the highest risk of RSV-related hospitalisation, infants born between 32 and 36 weeks have the highest proportion of RSV hospitalisation in infants overall.[22]

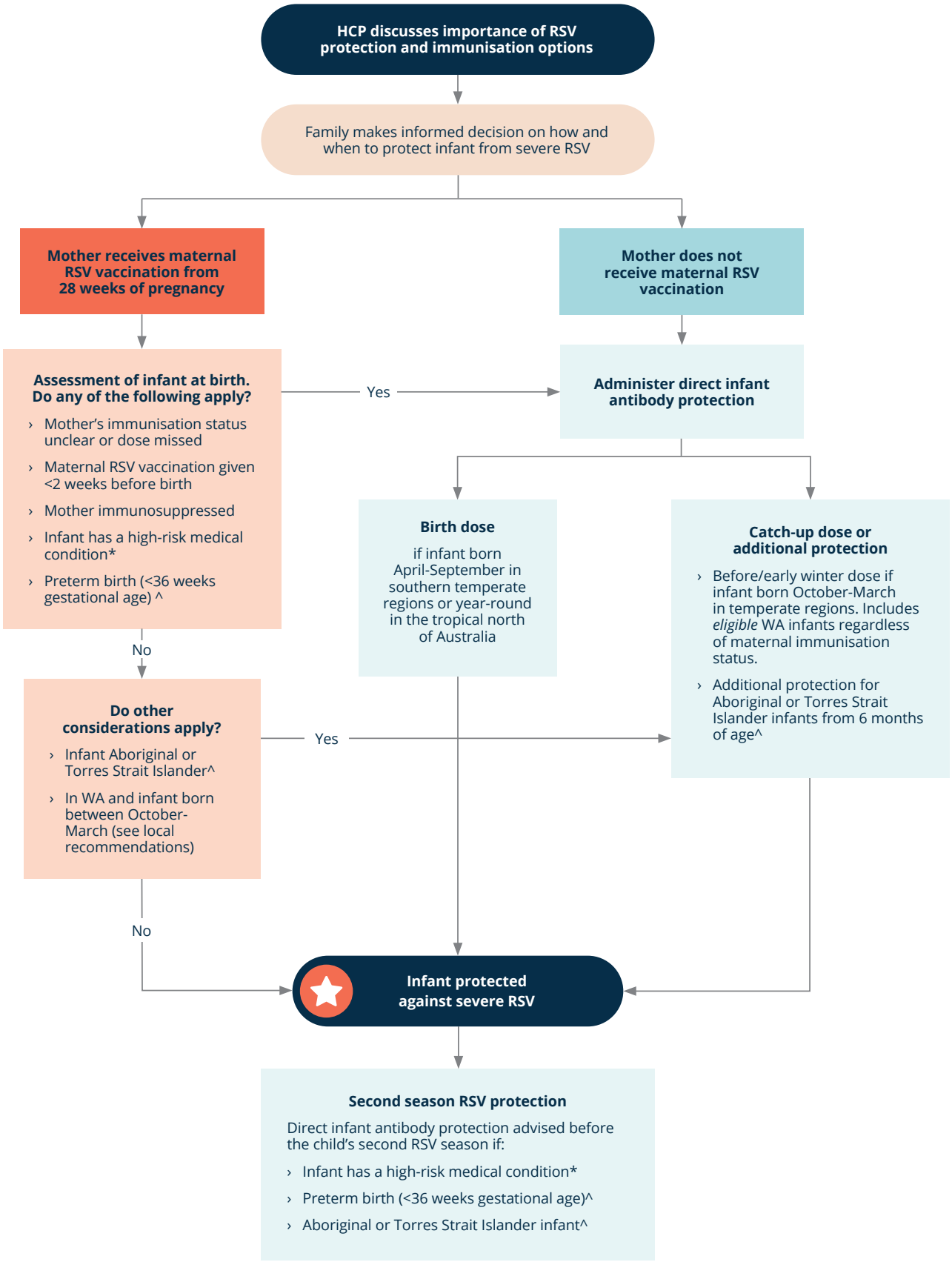
Healthcare providers should discuss RSV protection with new parents, as well as review the Australian Immunisation Register to confirm immunisation status. If there is uncertainty around whether the infant has been adequately protected through maternal immunisation, the provider should administer RSV antibody protection to the infant.

Studies have not identified safety concerns in infants receiving both maternal and infant antibody immunisation, providing reassurance given coverage for both options is recommended for infants with additional risk factors for severe RSV disease (refer Table 1).[23,24]

The dual offering of maternal vaccination and direct infant immunisation provides all-important choice for parents and healthcare professionals and acknowledges both the practical considerations and personal preferences that can significantly impact immunisation acceptance and uptake.

PROPOSED NATIONAL PATHWAY FOR INFANT RSV PROTECTION

This pathway illustrates how maternal RSV vaccination and direct infant antibody protection can work together to better protect Australian infants from RSV. This may not reflect current federal, state, or territory guidance and funding arrangements.



*Refer to Table 1 for additional risk factors for severe RSV disease.
^Recommended revisions to the Australian Immunisation Handbook – additional risk factors for severe RSV disease.
Refer to Approved Product Information before prescribing any immunisation.

BARRIERS TO OPTIMAL PROTECTION

Australia's dual immunisation RSV-MIPP is not funded or delivered as a single national program. Instead, responsibility is split between the federal and state or territory jurisdictions.

This funding and administrative divide is a major barrier to optimal infant RSV protection. Access and availability must be uniform so that all Australian infants are afforded effective protection against severe RSV.

Until recently, the legislative framework underpinning the NIP defined 'vaccines' in a way that excluded monoclonal antibodies. This prevented the Pharmaceutical Benefits Advisory Committee from making a positive funding recommendation, irrespective of clinical benefit or cost-effectiveness.

The RSV-MIPP was intended to expedite nationwide, all-infant RSV protection within these constraints. But its split funding model has contributed to a fragmented rollout, inconsistent messaging, and uncertainty regarding the roles of each immunisation.

Providers and families have been left to navigate unnecessary complexity, increasing the risk that infants miss out on RSV protection altogether.

Equity gaps are most acute for Aboriginal and Torres Strait Islander infants and families in remote communities, where antenatal and postnatal care attendance is less consistent, cold-chain logistics are more complex, and healthcare workforce capacity is stretched.

Inconsistent communication compounds the problem, leaving providers and families uncertain about which immunisation is most appropriate, when, and for whom.

In some parts of Australia, doses require pre-ordering on an individual infant basis, or provisions are restricted to hospital-based providers only, while other jurisdictions champion wide, dual access pathways across multiple settings.

Including infant antibody protection on the NIP would resolve many of the issues resulting from jurisdictional variability and support simplicity across all aspects of the RSV-MIPP. Importantly, it would allow the Commonwealth Government to negotiate an overarching contract and price with the sponsor company/s, streamline public health messaging, encourage the antibody to be stocked by all immunisation providers, and improve equity of access.

Role of improved data collection

A growing body of evidence from local and international infant RSV programs is helping to shape the country's approach and ensure the maximum number of infants are protected from severe RSV.

Robust, nationally coordinated data collection is essential to optimise Australia's dual immunisation RSV program and ensure the right intervention reaches the right infant at the right time.

Linking maternal vaccination, infant immunisation, and health outcome data would provide a clearer understanding of gaps in infant RSV protection.

This is critical to understanding how different strategies should be best integrated in clinical practice, such as streamlining eligibility criteria, understanding the effectiveness of each immunisation and targeting high-risk groups more effectively.

Moreover, data integration will shed light on ideal immunisation timing in the context of RSV seasonality, which peaks in winter in southern temperate Australia where the majority of the population lives.

KEY RECOMMENDATIONS TO OPTIMISE INFANT RSV PROTECTION

01	**Affirm the dual immunisation program model**	Support the use of RSV maternal vaccination and direct infant antibody protection, while avoiding framing these two immunisations as competing options. Population-level protection should be emphasised in the design and communication of the RSV-MIPP, with clear guidance on when either or both immunisations should be used.
02	**Promote broad maternal immunisation**	Offer maternal RSV vaccination to all pregnant women from 28 weeks of gestation without routine exclusion, while integrating it into standard antenatal care throughout obstetrics, general practice, pharmacy, and midwifery. Administration alongside maternal influenza and pertussis vaccines should be supported where appropriate.
03	**Strengthen direct infant antibody protection use**	Prioritise high-risk infants and those not protected by maternal vaccination, including those born preterm at less than 36 weeks, those born within 14 days of maternal vaccination, and others at increased risk of severe RSV disease, while supporting 'birth-dose' and 'catch-up' delivery with clear access pathways. Additionally, review emerging data to determine the role of direct infant antibody protection where the requirement for RSV protection extends beyond the approximated six months provided by maternal vaccination, including infants born outside of a typical RSV season.[25]
04	**Ensure national consistency**	Support the inclusion of direct infant antibody protection in national frameworks, including the NIP, providing cost effectiveness is demonstrated. In the interim, improve alignment of eligibility criteria, timing and communication across states and territories to enhance clarity and uptake.
05	**Prioritise equity**	Ensure equitable access to RSV protection for all infants, regardless of where they live. Implement targeted strategies to enhance access for Aboriginal and Torres Strait Islander infants and remote communities.
06	**Simplify communication and education**	Develop clear, nationally aligned decision-support tools for healthcare professionals and families. Consistent and cohesive messaging across the nation is essential to reduce confusion and support informed decision-making.
07	**Improve provider workflows**	Reduce logistical barriers, improve data collection, and integrate RSV prevention into routine antenatal, postnatal, and infant care pathways in a nationally consistent manner.

THE REALITIES OF SEVERE RSV IN INFANTS

TWINS CHLOE AND MACIE

"Born six weeks early, Chloe and Macie were healthy newborns, and we were happy parents. Five weeks later, our world turned upside down.

Chloe was the first to get sick. She was floppy, lethargic and working hard to breathe – her skin was sucking in around the ribs and collarbone.

We took her to hospital where they confirmed RSV.

Two days later, Macie got sick.

We were back at the hospital when Macie became very distressed and panicked. Suddenly, my little girl stopped breathing in my arms.

She didn't take a breath for at least a minute, but it felt like a lifetime.

The medical team couldn't help straight away. Due to infectious disease protocols, they needed to gown up with personal protective equipment before rushing into the room.

We were on our own. Time stood still.

After Macie was resuscitated, I insisted my babies were sent to Perth. As soon as the Newborn Emergency Transport Service team saw the twins, they put them on high-level oxygen support.

The girls were kept in the neonatal intensive care unit at Perth Children's Hospital for two weeks, during which Macie developed pneumonia resulting in a collapsed lung.

RSV was beyond traumatising. I honestly thought the twins were both going to die.

Seeing my babies so sick, being poked and prodded, I don't think it's something that will ever leave me. I don't think I'll ever unsee or unfeel that experience."

Dione Nesbitt,
Albany, Western Australia

CONCLUSION

The advent and availability of infant RSV immunisations was a landmark achievement in public health, but fundamental changes are needed to ensure Australia's RSV dual immunisation program delivers on its full potential.

This consensus statement calls for coordinated effort to enhance Australia's RSV Mother and Infant Protection Program, notably through the inclusion of infant antibody protection on the NIP, greater focus on equity and ease of access, and evidence-based guidance to ensure the right RSV immunisation is provided to the right infant at the right time, no matter where they live.

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