Respiratory syncytial virus prevention is finally here: An overview of safety

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Background
A number of respiratory syncytial virus (RSV) prevention products have recently been approved in Australia. These products focus on highest risk groups, aiming to prevent RSV disease in young infants and older adults. While not currently included in the National Immunisation Program (NIP), an RSV vaccine (Arexvy, GlaxoSmithKline [GSK]) is available privately for adults ≥60 years, and some Australian jurisdictions have commenced RSV monoclonal antibody (nirsevimab) programs for infants in 2024.

Objective
This article summarises safety data regarding RSV prevention products approved in Australia, including vaccines for adults ≥60 years, maternal vaccines and monoclonal antibodies for infants.

Discussion
Clinical trial data found these products were largely well tolerated, with most local and systemic reactions being mild–moderate and short-lived. Proportions of serious adverse events were low. While very rare, potential safety signals being further assessed include risk of preterm birth following the maternal vaccine (Abrysvo, Pfizer) and Guillain–Barré syndrome (GBS) following RSV vaccines in older adults (Abrysvo and Arexvy). Close monitoring of these adverse events of special interest via post-licensure surveillance is underway.

RESPIRATORY SYNCYTIAL VIRUS (RSV) is an RNA virus, with two subtypes (A and B), causing respiratory tract infections. The greatest illness burden impacts children <2 years of age, with highest risk for infants <6 months, premature infants and those with susceptible medical conditions.[1,2] Older adults, and individuals with medical risk factors are also at higher risk for severe RSV disease.[3] In Australia, RSV infections cause over 6000 hospitalisations annually, at significant cost to the health system.[4,5] RSV predominantly occurs over winter, noting changes in seasonality during the COVID-19 pandemic.[6] Tropical areas of Australia have a less predictable RSV season.

Multiple new RSV prevention products have recently been licensed. The development of RSV vaccines has had a long, complex history. In particular, cases of vaccine-associated enhanced disease following a formalin-inactivated RSV vaccine in the 1960s in the USA stalled the progress of RSV vaccine development considerably.[7]

The products recently approved appropriately focus on highest risk periods, aiming to prevent severe RSV disease in infants and older adults. Existing safety data come primarily from clinical trials, but with the commencement of RSV prevention programs internationally, post-licensure (phase IV) data are increasingly becoming available. By pooling large numbers of vaccinees, post-licensure surveillance is better powered to detect rare adverse events.

Aim

This article summarises safety data regarding RSV prevention products, focusing on products approved in Australia by the Therapeutic Goods Administration (TGA). To date, no products have been included in the National Immunisation Program (NIP), but a number have been or are currently under review by the Pharmaceutical Benefits Advisory Committee.[8,9]

Vaccines for older adults

Two RSV vaccines have been approved for adults ≥60 years in Australia: Arexvy, the GlaxoSmithKline (GSK) RSV vaccine and Abrysvo, the Pfizer RSV vaccine.[10,11] Both are currently recommended as a single-dose course, and can be given at any time of year.

Arexvy and Abrysvo are both recombinant vaccines containing RSV pre-fusion F protein antigen. They come as powder and suspension for injection, requiring reconstitution to make up 0.5 mL for intramuscular injection. Diluent components are different for each vaccine.

Arexvy contains antigen derived from the RSV-A subtype and uses the same highly reactogenic adjuvant as the Shingrix vaccine ($AS01_E$), although at a reduced dose.[10] Arexvy is currently available through private prescription. It is recommended by the Australian Technical Advisory Group on Immunisation (ATAGI) for all adults ≥75 years, Aboriginal and Torres Strait Islander peoples aged 60–74 years, and adults aged 60–74 years with higher-risk medical conditions.[12]

Abrysvo contains antigen components for both RSV-A and RSV-B subtypes and is not adjuvanted. It is registered for adults ≥60 years, and in pregnancy (see Vaccines in pregnancy).[11]

Clinical trial vaccine efficacy estimates for both vaccines were high, with an 83% reduction in RSV-associated lower respiratory tract disease (LRTD) demonstrated for Arexvy and 89% reduction in RSV-associated LRTD for Abrysvo, across one RSV season.[13,14]

Arexvy is a relatively reactogenic vaccine. Common local reactions included injection site pain, redness and swelling. Common systemic symptoms included fatigue, myalgia and headache.[10,15] In Arexvy clinical trials in older adults, including 18,304 vaccinees, a case of Guillain–Barré syndrome (GBS), and two cases of acute demyelinating encephalomyelitis (ADEM) were reported within six weeks of vaccination.[16] Subsequent investigator review led to the latter two cases being assessed as not consistent with ADEM.[10]

Common local and systemic symptoms following Abrysvo included injection site pain, redness and swelling, headache and myalgia.[11,15,17] In Abrysvo clinical trials in older adults, including 20,255 vaccinees, two cases of GBS were reported within six weeks of vaccination.[11,16]

These initial findings meant that the US Food and Drug Administration (FDA), as a condition of vaccine approval, required both manufacturers to conduct additional research.[18,19] This is important, as establishing causal links between vaccines and rare outcomes, such as GBS, is often difficult. In addition, GBS and other inflammatory neuropathies are subject to ongoing enhanced surveillance internationally. By 30 March 2024, approximately 3.4 million and 7.2 million adults aged ≥60 years in the USA had received Abrysvo and Arexvy respectively. Post-licensure data from the USA's Vaccine Adverse Event Reporting System (VAERS), a passive surveillance system, recently reported the equivalent of 4.4 and 1.8 GBS cases per million doses of Abrysvo and Arexvy respectively, exceeded expected background rates.[15] Recent self-controlled case series analyses from the USA did not find a statistically significant association between GBS and RSV vaccines in older adults.[20] Further research is underway.

Co-administration of these RSV vaccines with other vaccines is permitted, but (as with any vaccine co-administration) might result in an increased risk of local and systemic side effects. This might be more likely, for example, if Arexvy were co-administered with other adjuvanted vaccines, such as adjuvanted influenza vaccines and/or Shingrix. This is best addressed as a risk-benefit discussion with patients, considering individual context and preferences, noting the importance of minimising missed vaccination opportunities.

Vaccines in pregnancy

Maternal vaccination provides passive immunity, via placental transfer of antibodies, to infants in the months after birth. It also has the benefits of protecting mothers in the peripartum period and offering infants additional protection through breastfeeding.

Development of maternal RSV vaccines has not been straightforward. An initial RSV vaccine trial demonstrated proof of concept and safety but was discontinued in the setting of limited vaccine efficacy.[21] Following this, GSK maternal RSV vaccine trials were also discontinued following an imbalance in preterm births. The higher number of preterm births among vaccinated groups was not consistent across sites (only noted in some countries, during certain periods) but nevertheless meant the trial was halted.[22,23] Considerable post-hoc analysis has attempted to better understand the preterm birth imbalance, with reasons remaining unclear.[24]

Abrysvo has been registered for use in pregnancy between 24 and 36 weeks' gestation in Australia.[11] It is licensed as a single-dose course; in the future this might change to being recommended in each pregnancy. Co-administration with other vaccines in pregnancy, such as influenza- and pertussis-containing vaccines, is permitted.

Clinical trials of Abrysvo in pregnancy indicated vaccine efficacy of 69% in preventing medically attended severe RSV-associated lower respiratory tract illness (LRTI) and 57% in preventing RSV-associated hospitalisation among infants in the first six months.[25]

For mothers, injection site pain was the most common local reaction. Fatigue, headache and muscle pain were the most common systemic reactions, noting fatigue commonly preceded immunisation, and was not different to placebo.[25] Proportions of serious adverse events were rare, and similar across vaccine and placebo groups.[11,25,26] For infants, proportions of any adverse events, and any serious adverse event up to 24 months were the same across vaccine and placebo groups. No serious adverse events in infants were considered related to maternal vaccination.[25,26]

There was an imbalance in preterm births in Abrysvo clinical trial data, noting the difference was not statistically significant, and a causal relationship could not be established.[27] In light of this finding, the FDA approved Abrysvo for administration later in pregnancy (32–36 weeks) to minimise potential for early preterm birth.[27,28] Balancing protection for premature infants and any potential (rare) risk of preterm birth, ATAGI recommends Abrysvo between 28 and 36 weeks.[12] The UK also recommends Abrysvo from 28 weeks.[29]

Monoclonal antibodies for infants and young children

Monoclonal antibody products provide infants with passive immunity. There are no RSV vaccines currently available for children.

Palivizumab (Synagis, AstraZeneca) is a monoclonal antibody in use in Australia since 1999. It is restricted to highest-risk infants, usually as part of hospital-based programs. It requires monthly injections over the first RSV season.[30] Palivizumab remains an alternative to newer monoclonal antibodies for high-risk infants, particularly given supply shortages.

Nirsevimab (Beyfortus, Sanofi-Aventis) is a new monoclonal antibody registered by the TGA in 2023, which has already been introduced in some state-base programs.[31] It comes as a pre-filled syringe, with weight- and age-dependent dosing (Table 1). A single dose offers protection against RSV infection for approximately five months. Nirsevimab is approved for all infants (of any gestation) in their first year, either at birth or in time for their first RSV season. In higher-risk children (aged <24 months) an additional dose can be considered in their second RSV season.[12, 32]

ATAGI recommendations are summarised in Table 1.[12] Co-administration with NIP vaccines is permitted. While not a vaccine, as a passive immunisation, doses can be recorded in the Australian Immunisation Register.

Clinical trial estimates of nirsevimab's efficacy in preventing medically attended RSV-associated LRTI were 70 to 75%,[33–35] and 75 to >80% in preventing hospitalisation from RSV-associated LRTI.[36, 37] Early evidence from nirsevimab programs in

Table 1. Summary of new RSV prevention products

Age group	Prevention product	Safety information[A]
Adults ≥60 years Arexvy is available via private prescription in Australia. Both Arexvy and Abrysvo not currently included in NIP	**Arexvy:** recombinant vaccine containing RSV pre-fusion F protein antigen and an adjuvant; requires reconstitution; 0.5 mL for intramuscular injection	• Local injection site reactions: 44%[15] • Systemic symptoms: 37%[15] • Mostly mild–moderate and short-lived
	Abrysvo: recombinant vaccine containing RSV pre-fusion F protein antigen; non-adjuvanted; requires reconstitution; 0.5 mL for intramuscular injection	• Local injection site reactions: 20%[15] • Systemic symptoms: 22%[15] • Mostly mild–moderate and short-lived
	Recommended for all adults aged ≥75 years; Aboriginal and Torres Strait Islander people aged 60–74 years; and adults aged 60–74 years with higher-risk medical conditions (no vaccine brand preference)[12]	• For both vaccines, serious adverse events rare; potential risk of neurological events (GBS, ADEM) still being assessed[14,15]
Pregnant people Not currently included in NIP	**Abrysvo:** as above Immunisation in pregnancy to provide passive immunity to infants during first 6 months after birth, recommended by ATAGI for administration between 28 and 36 weeks[12]	• Local injection site reactions (within 7 days of vaccination): up to 43%[26] (vs placebo group 10%) • Systemic symptoms (within 7 days of vaccination): up to 64%[26] (vs placebo group 59%) • Mostly mild–moderate and short-lived • Serious adverse events rare; potential risk of preterm birth still being assessed[27]
Infants <24 months Nirsevimab is available through varied state-based programs (WA, Qld, NSW); not currently included in NIP	**Nirsevimab:** long-acting monoclonal antibody, pre-filled syringe(s) for intramuscular injection First RSV season: • 50 mg in 0.5 mL if <5 kg (purple plunger rod) • 100 mg in 1 mL if ≥5 kg (light blue plunger rod) Second RSV season, for children at increased risk only: 200 mg, given as 2 x 100 mg injections in different sites Recommended for all infants <8 months, unless infant's mother received RSV vaccine ≥2 weeks prior to delivery AND infant is not high-risk for severe RSV disease. An additional dose can be considered for higher-risk children (<24 months) in their second RSV season. See Australian Immunisation Handbook for full recommendations.[12]	• Reactions mostly mild and short-lived; rash, injection site reaction and fever uncommon (<1%)[41] • More serious side effects extremely rare; hypersensitivity reactions still being monitored[40] • Increased potential for vaccine administration errors given dosing complexity (note the dose for second season use is 4 times the newborn dose)

[A]Safety information for vaccines in older adults references post-licensure data from USA (Vaccine Adverse Event Reporting System). Data referenced for products in pregnant people and infants are from clinical trials.

ADEM, acute demyelinating encephalomyelitis; ATAGI, Australian Technical Advisory Group on Immunisation; GBS, Guillain–Barré syndrome; NIP, National Immunisation Program; RSV respiratory syncytial virus.

the USA and Europe have demonstrated real-world vaccine effectiveness between 70 and 90%.[38,39]

Overall safety data have been highly reassuring, with most infants tolerating the medication well. In clinical trials, the most common adverse events were upper respiratory tract infection, nasopharyngitis, fever and nappy rash.[31,35] Adverse events assessed as likely treatment-related occurred for 1.3% of infants vaccinated, which was similar to placebo.[35] Reactions were usually mild and short-lived. No serious adverse events considered related to nirsevimab occurred in clinical trials.[32–37] Post-licensure in the USA, there have been extremely rare reports of hypersensitivity, with features including 'urticaria, dyspnea, cyanosis and/or hypotonia'.[40] From a practical standpoint, the complexity of different doses (Table 1) also increases the potential for vaccine errors.

Implications and future considerations

The range of emerging RSV prevention products presents an extraordinary opportunity to prevent significant morbidity and mortality from RSV infection. They also present challenges for policy makers and immunisation providers in imbedding these products in an increasingly busy and complex immunisation schedule, and supporting patients and parents to make informed decisions. Risk-benefit discussions take time and, as well as understanding characteristics of the products, require an appreciation of RSV disease, which has had relatively low public awareness. The next years will be important in providing further data regarding real-world safety and effectiveness of these products.

Key points

- RSV prevention products recently approved in Australia include vaccines for adults ≥60 years, maternal vaccines and monoclonal antibodies for infants.
- These products focus on preventing RSV disease in infants and older adults, representing those at highest risk.
- As well as data from clinical trials, post-licensure vaccine safety data are increasingly becoming available, following commencement of RSV prevention programs internationally.
- Existing data indicate these products are largely well tolerated, with most local and systemic reactions being mild–moderate and short-lived.
- While very rare, potential safety signals being further assessed include risk of preterm birth following the maternal vaccine (Abrysvo) and Guillain–Barré syndrome following RSV vaccines (Abrysvo and Arexvy) in older adults.

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