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ATAGI Targeted Review 2024: Immunisation strategies for prevention and control of respiratory syncytial virus disease in Australia

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Abstract

Respiratory syncytial virus (RSV) causes lower respiratory tract infection and severe disease, particularly in infants, and is increasingly recognised as a cause of major morbidity and mortality in the elderly. Several new vaccines aim to address the disease burden at both extremes of the age spectrum. Immunisation using a long-acting monoclonal antibody is also available for infants and young children. In 2025, a comprehensive RSV maternal and infant protection program commenced with a nationally coordinated maternal RSV vaccination in pregnancy on the National Immunisation Program and long-acting monoclonal antibody for infants and children funded by states and territories.

This targeted review outlines the Australian Technical Advisory Group on Immunisation's considerations and the evidence informing policy decisions on an RSV prevention strategy for Australia. Review of the burden of RSV disease in Australia indicates specific populations which would derive the most benefit from effective immunisation, including the very young; the elderly; First Nations people; and those with underlying medical risk factors. However, some data gaps exist in our understanding of RSV disease, particularly non-hospitalised disease and disease in adult age groups. The available evidence points to promising efficacy, against severe RSV disease, of three RSV vaccines in older adults, as well as the single available vaccine for use in pregnancy for protecting infants in the first six months of life. A long-acting RSV-specific monoclonal antibody, nirsevimab, has been highly effective in young infants in early assessments; however, there is a need to accumulate more information as these products expand in use. For RSV vaccines, there is a need to monitor duration of protection and safety, to inform the need for repeat vaccine doses in older adults and in subsequent pregnancies. As RSV immunisation involves new vaccines and monoclonal antibodies, it is important that a robust program monitoring and evaluation plan is put in place, to optimise assessment of vaccine uptake, patient acceptance and the impact of the interventions on RSV disease, with appropriate safety monitoring to facilitate public confidence in the immunisation program.

Keywords: respiratory syncytial virus (RSV); Australian Technical Advisory Group on Immunisation (ATAGI); National Immunisation Technical Advisory Group (NITAG); immunisation; Australia

Introduction

Respiratory syncytial virus (RSV) is a leading cause of lower respiratory tract infections (LRTI) and hospitalisation in young children. More recently it is also recognised as a significant cause of illness among adults. RSV infection generally results in a mild self-limiting illness; however, in vulnerable populations, it can be severe. The populations at particularly increased risk of severe RSV disease and associated death include young infants, especially those born preterm; older adults; and individuals with certain underlying medical conditions, as listed in the Australian Immunisation Handbook.[1–3] Despite RSV infections resulting in substantial morbidity and mortality for society, until very recently, palivizumab, an RSV monoclonal antibody preparation for passive immunisation of high-risk infants, was the only available pharmacological prevention strategy. Due to its cost and the need for monthly administration during the RSV season, the use of palivizumab has been limited to infants at the highest risk of severe RSV through state or hospital-funded programs in Australia.[4]

Since late 2023, three new RSV vaccines have been registered for use in adults aged 60 years and older, with one of these vaccines (Arexvy, GSK) also indicated for adults aged 50–59 years with conditions which increase the risk of severe disease, and another (Abrysvo, Pfizer) for vaccination during pregnancy to protect infants in the first six months of life. A *long-acting* monoclonal antibody (nirsevimab [Beyfortus], Sanofi) has also been registered to protect both infants and selected high-risk children in the second year of life via passive immunisation. Some states and territories (i.e. Queensland, New South Wales, the Australian Capital Territory, Tasmania, and Western Australia) commenced jurisdictionally-funded nirsevimab immunisation programs for the 2024 RSV season.

The availability of these RSV immunisation products facilitates potential implementation of a broad and effective strategy for RSV prevention among vulnerable populations. Throughout 2023 and 2024, the Australian Technical Advisory Group on Immunisation (ATAGI) worked extensively to inform RSV prevention policy and program advice. In June 2024, ATAGI first published recommendations on the use of RSV immunisation products in the Australian Immunisation Handbook, following interim statements on one adult RSV vaccine and on nirsevimab, respectively, earlier in 2024.[3] In 2025, the National RSV Maternal and Infant Protection Program (RSV-MIPP) commenced, providing a comprehensive approach to infant RSV prevention, and combining maternal vaccination using Abrysvo in pregnancy on the National Immunisation Program (NIP) and state- and territory-funded long-acting monoclonal antibody programs for infants and children.

This ATAGI Targeted Review aims to summarise the evidence, underpinning the current ATAGI recommendations for relevant target Australian populations, on the need and the potential benefit of an RSV immunisation program. This review also highlights the current RSV immunisation recommendations internationally, in particular in the United States of America (USA) and the United Kingdom (UK) which have either already initiated or plan to implement population-based programs. The potential future directions of the Australian RSV immunisation program are also outlined in the review. This report reflects information available up to early July 2025.

RSV epidemiology in Australia

Overview of RSV epidemiology in Australia

Table 1 summarises age-specific RSV hospitalisation rates in Australia derived from a range of population-based published and unpublished data sources. The annual rate of RSV-associated hospitalisations is highest in infants aged < 3 months and declines thereafter with age, until the age of 50–65 years after which rates progressively increase.[5-8] An analysis by the National Centre for Immunisation Research and Surveillance (NCIRS) using the Australian Institute of Health and Welfare National Hospital Morbidity Database (AIHW NHMD) records (Table 1) showed that in the period of 2016–2019, approximately 50% of the total RSV-coded hospitalisations (*International Classification of Diseases* [ICD], *tenth revision*, *Australian modification* codes for RSV pneumonia [J12.1], RSV bronchitis [J20.5], RSV bronchiolitis [J21.0], and RSV organisms [B97.4]) in Australia occurred in young children aged < 24 months; the annual rate was highest in infants aged < 3 months at 4,014 per 100,000 population. While the RSV-associated hospitalisation rate is highest in young infants, the annual in-hospital case fatality rate for RSV hospitalisations was highest in older adults. A similar pattern in RSV hospitalisation and mortality by age is reported in a global review of RSV disease burden.[9]

Table 1: Summary of estimates of age-specific annual respiratory syncytial virus (RSV) hospitalisation rates in Australia from various studies

Category	Age group	Study scope/findings				
Study reference	—	**5**	**6**	**7**	**8**	**NCIRS 2024[a]**
Study site	—	Western Australia	New South Wales	Australia	Australia	Australia
Time period	—	2000–2012	2001–2010	2009–2017	2006–2015	2016–2019
Data	—	Linked laboratory, perinatal and hospitalisation data	Linked hospital, perinatal and NICU data[b]	Hospitalisation data	Hospitalisation data	Hospitalisation data
RSV case ascertainment[c]	—	Laboratory-confirmed RSV infection	ICD code; primary diagnosis only	ICD code; primary diagnosis only	ICD code; primary or other diagnosis	ICD code; primary or other diagnosis
RSV outcome	—	Predicted estimates of RSV hospitalisation	RSV-coded hospitalisation	Modelled RSV-attributable ARI hospitalisation[d]	RSV-coded hospitalisation	RSV-coded hospitalisation
Hospitalisation rates per 100,000 population per year (95% CI)[e]	0 month	2,400 (2,230–2,580)	2,560 (2,390–2,530)	590 (467–720)	3,129	4,014
	1 month	4,370 (4,210–4,540)				
	2 months					
	3 months	2,790 (2,680–2,900)			1,806	2,177
	4 months		1,670 (1,620–1,740)			
	5 months					
	6 months	1,280 (1,230–1,340)	470 (450—480)		1,032	1,294
	7 months					
	8 months					
	9 months					
	10 months					
	11 months					
	12–23 months	530 (500–550)	280 (270–290)		500	755
	24–59 months	—	27 (25–31)		92	147

Category	Age group			Study scope/findings		
	5–14 years			-4 (-30–24)	6	10
	15–19 years			4 (-10–18)	1	7
	20–24 years					
	25–34 years				1	
	35–44 years				2	
	45–49 years	—	—	4 (-17–24)	3	26
	50–54 years					
	55–64 years				7	
	65–69 years			34 (-32–104)	21	53[f]
	70–74 years					81[f]
	75+ years			256 (5–487)		196[f]

a NCIRS: National Centre for Immunisation Research and Surveillance.

b NICU: neonatal intensive care unit.

c ICD: International Classification of Diseases.

d ARI: acute respiratory illness.

e CI: confidence interval.

f Rates were calculated based on hospitalisation records of adults who were not identified as Aboriginal or Torres Strait Islander peoples, since hospitalisation records are only available for analysis as aggregated data for all Aboriginal and Torres Strait Islander peoples aged ≥ 65 years.

Before the coronavirus disease 2019 (COVID-19) pandemic commenced in early 2020, RSV activity in most areas of Australia had a distinct annual epidemic pattern through autumn and winter that peaked in June–July. This seasonality was less pronounced in the Northern Territory.[10] As observed in other countries, during the 2020–2021 COVID-19 pandemic years, RSV activity in Australia declined considerably, largely eliminating the normal seasonal pattern. While RSV became a notifiable condition across Australia under the National Notifiable Diseases Surveillance System (NNDSS) in 2021, variable implementation by states and territories has meant that the data are considered complete only from 2023 onwards. Nevertheless, available data from 2022–2023 national laboratory-confirmed RSV notifications suggest a return towards the pre-pandemic seasonality pattern following the relaxation of COVID-19 travel restrictions and non-pharmacological interventions.

Infants

Among infants, RSV disease burden is particularly high in those born preterm. In a prediction model using linked perinatal, hospitalisation, and laboratory records from 2000 to 2012 in Western Australia,[12] RSV hospitalisation rates in the first year of life were significantly higher if born at < 37 weeks gestation compared to full term birth (i.e. ≥ 37 weeks gestational age; Table 2). A study that used similar linked data from 2001 to 2010 in New South Wales, for children up to age 5 years, reported approximately five and eight times higher RSV hospitalisation rates in those born at < 28 weeks and 28–31 weeks of gestation, respectively, compared to the overall population rate in those aged < 5 years.[6]

Most disease in Australian infants (aged < 12 months) occurs during the RSV season (April to September), with the 2016–2019 NHMD records showing approximately 80% of annual RSV-coded hospitalisations occurring during these months. However, the inter-season burden also remains substantial in this age group, with estimated RSV hospitalisation rates remaining approximately 500 per 100,000 population per year, exceeding the annual rates for any other age group > 2 years.

Older adults

The burden of severe RSV disease in older adults increases substantially with age. In the years prior to the COVID-19 pandemic, the 2016–2019 NHMD records showed that approximately 70% of ICD-coded RSV hospitalisations in Australian adults aged ≥ 65 years occurred in those aged ≥ 75 years (196 per 100,000 population per year, Table 1). However, these observed rates are likely to be an under-estimation, particularly during earlier years, with a trend to increased testing for RSV over time during this period in older adults. This is substantiated by an eight-fold increase in RSV-coded hospitalisation rates in adults aged ≥ 65 years between 2012 and 2019. This was much greater than the increase in infant RSV-coded hospitalisations seen over this same period (a 1.3-fold increase in hospitalisation rates from 2012 to 2019 among infants aged < 12 months), where testing of hospitalised children with respiratory illness is common practice to assist in diagnosing bronchiolitis and to manage infection control. More research is required to better understand RSV hospitalisation trends in adults aged ≥ 65 years and the role of increased testing as compared with true increases, potentially related to population ageing and/or increasing prevalence of comorbid conditions which increases risk.

Table 2: Predicted annual respiratory syncytial virus (RSV) hospitalisation rates in infants by gestational age in Western Australia,[a] 2000–2012

Gestational age at birth	Age at admission < 6 months		Age at admission 6–11 months	
	Predicted rate[b]	95% CI[c]	Predicted rate[b]	95% CI[c]
≤ 28 weeks	6,140	4,640–8,120	1,260	1,090–1,450
29–32 weeks	12,760	11,230–14,500	1,420	1,300–1,550
33–36 weeks	5,920	5,510–6,360	550	520–580
≥ 37 weeks	2,950	2,870–3,030	270	270–280
Overall	**3,270**	**3,180–3,350**	**310**	**300–310**

a These data were provided for this report by the authors.[12]

b Rate per 100,000 population per year.

c 95% CI: 95% confidence interval.

A study using 2009–2017 hospitalisations data attempted to account for underestimation in RSV-attributable disease by using statistical modelling. It estimated annual RSV-attributable acute respiratory infection hospitalisation rates to be 256.4 (95% confidence interval [95% CI]: 5.3–487.4) per 100,000 population among Australian adults aged ≥ 75 years.[7] This estimate for Australian adults, although imprecise, was somewhat higher than that reported for the same age group estimated across high-income countries (183.8 (interquartile range [IQR]: 144.4–337.4) per 100,000 population per year) from a systematic review of modelling studies of RSV hospitalisation and mortality burden.[9]

Further studies, including those that incorporate alternative methods such as statistical modelling or sentinel hospital surveillance with active case ascertainment, are warranted to better understand the true hospitalisation burden associated with RSV infections in older Australians.

Priority population: Aboriginal and Torres Strait Islander peoples

Aboriginal and Torres Strait Islander (hereafter respectfully referred to as *First Nations*) peoples are at a greater risk of severe RSV illness, likely due to the higher prevalence of underlying medical risk conditions and longstanding social and health inequities. However, incomplete and inaccurate identification of First Nations people in population and health administrative data limits accurate assessment of the RSV disease burden, particularly among older First Nations people. While the true risk of RSV disease among First Nations people remains unclear, the 2016–2019 NHMD records suggest that their burden of disease is comparable to that of other Australians, but occurs at younger ages. During this period, the RSV hospitalisation rate among First Nations adults aged 60–64 years (93 [95% CI: 76–113] per 100,000 population per year) was approximately equivalent to that of non-Indigenous Australian adults aged 70–79 years (97 [95% CI: 95–100] per 100,000 population per year). In First Nations children aged < 2 years, hospitalisation rates were approximately twice as high as for other Australian children.

These findings illustrate that First Nations adults experience an equivalent risk of severe RSV disease at comparatively younger ages than other older Australians and that in the vulnerable younger age group, First Nations children aged < 2 years also have an increased burden of RSV disease.

Priority population: Adults with medical conditions that increase risk of severe RSV disease

Table 3 summarises a review of studies published up to June 2023 which explore underlying conditions associated with severe clinical outcomes of RSV infection such as hospitalisation; mortality; other complications (e.g. pneumonia); admission to an intensive care unit (ICU); and requirement for ventilatory support among adults aged ≥ 18 years. Chronic respiratory disease, cardiac disease, immunocompromising conditions, and chronic renal disease were commonly reported in the identified studies as the conditions associated with increased risk of severe RSV disease and associated mortality.

Table 3: Conditions associated with increased risk of severe respiratory syncytial virus (RSV) disease[a] or mortality in adults based on published studies, as of June 2023

Conditions[b]	Outcome						
	Hospital admission	ICU admission[c]	ED admission[d]	Other complication[e]	Ventilatory support	Length of stay[f]	Deaths
	Risk[g]	Risk[g]	Risk[g]	Risk[g]	Risk[g]	Risk[g]	Risk[g]
Chronic respiratory disease: chronic lung disease including COPD, asthma, bronchiectasis, or pulmonary fibrosis	Y[13–15]	–	Y[16]	Y[16,17]	Y[18]	Y[19]	Y[17]
Cardiac disease: CHF, CAD	Y[13–15,19–21]	Y[20]	Y[16]	Y[16]	–	–	Y[22]
Diabetes mellitus	Y[13–15]	–	–	–	–	–	–
Immunocompromising conditions: solid and haematological malignancy, immunosuppressive treatment	Y[21,23–25]	–	–	Y[26, 27]	–	–	Y[17,22,28]
Chronic renal diseases: CKD, end-stage renal failure	Y[13,21]	–	Y	Y[17]	Y[17]	–	Y[17,28]
Neurological condition: dementia	–	–	–	–	–	–	Y[22]
Assisted living: skilled nursing or long-term care facility, rehabilitation facility or hospice	–	Y[11]	–	–	Y[11]	–	Y[11]

a Indicators of severe RSV disease assessed by study varied.

b COPD: chronic obstructive pulmonary disease; CHF: congestive heart failure; CAD: coronary artery disease; CKD: chronic kidney disease.

c ICU: intensive care unit.

d ED: emergency department.

e Other complications: pneumonia; hyperventilation syndrome; or obstructive sleep apnoea.

f ICU length of stay.

g Is the identified condition, coupled with severe RSV disease, connected to an increased risk/duration of the identified outcome?

RSV vaccines and monoclonal antibodies

Vaccine for pregnant persons for protection of infants

In Australia, one RSV vaccine (Abrysvo, Pfizer) has been approved by the Therapeutic Goods Administration (TGA) for use in pregnant persons to provide passive immunisation to their infants against severe RSV illness. Administration of the vaccine during pregnancy leads to transplacental transfer of RSV-specific antibodies from the mother to the foetus. Clinical trial data show that maternal vaccination reduced the risk of medically attended severe LRTI in the infants by approximately 82% (99.5% CI: 41–96%) and 69% (97.58% CI: 44–84%) within 90 and 180 days after birth, respectively.[29] Trial data on protection beyond 180 days (6 months) of age are currently limited, but such protection is likely to be lower due to waning of maternally-derived antibodies.

In the phase 2 and 3 studies of Abrysvo, local adverse events (AEs) in vaccine recipients were more common than in the placebo groups (31.6–42.5% vs 10.4–13.7%), with injection site pain the most common event reported. However, there was no difference in the rate of systemic AEs between vaccine and placebo groups.

Clinical trials of RSV vaccination with Abrysvo during pregnancy at 24–36 weeks of gestation identified a numerical imbalance in preterm births (< 37 weeks gestation) between vaccine and placebo groups (202/3,568 [5.7% (95% CI: 4.9–6.5%)] vs 169/3,558 [4.7% (95% CI: 4.1–5.5%)], respectively; rate ratio [RR]: 1.20 [95% CI: 0.99–1.46]).[29] However, this difference was not statistically significant. As the clinical trials were not powered to detect such rare events, it is not clear whether there is a causative link between RSV vaccine and preterm birth. ATAGI is monitoring further evidence on any association with preterm births, including studies on post-licensure use in the general pregnant population. The Australian Immunisation Handbook recommends administration of Abrysvo in pregnancy from 28 weeks gestation onward, not 24 weeks, as a precautionary measure. At present, vaccination only in an initial pregnancy but not in subsequent pregnancies is recommended, as no data are currently available on revaccination with subsequent pregnancies. However, the need for vaccination during each pregnancy is anticipated based on evidence from other vaccines in pregnancy, such as influenza and pertussis. ATAGI will update advice on revaccination in subsequent pregnancies when clinical data become available.

Monoclonal antibodies for protection of infants

Direct administration of RSV-specific monoclonal antibodies is another effective method of passive immunisation of infants against severe RSV disease. Two monoclonal antibodies are currently available in Australia: palivizumab (Synagis) and nirsevimab (Beyfortus). Palivizumab has been registered since 1999 for use in infants at high risk of RSV disease, such as preterm infants and young children with congenital heart disease.[4] However, palivizumab requires monthly intramuscular injections to achieve and maintain a protective concentration of antibodies during an RSV season; its use in Australia has thus been very limited.[4,30]

Nirsevimab is a long-acting RSV-specific monoclonal antibody preparation given as a single intramuscular dose to provide protection for at least 5 months. It was approved by the TGA in November 2023 for the prevention of RSV-associated LRTI in neonates and infants born during or entering their first RSV season, and in children up to age 24 months who remain at increased risk for severe RSV disease in their second RSV season. It has advantages over palivizumab due to its enhanced viral neutralisation, longer duration of action, and requirement for only one injection for the RSV season. In clinical trials, efficacy against medically attended RSV-associated LRTI within 150 days after injection was 70.1% (95% CI: 52.3–81.2%) and 76.4% (95% CI: 62.3–85.2%) in infants born at 29–34 weeks and ≥ 35 weeks of gestation, respectively.[31,32] Efficacy against hospitalisation for RSV-associated LRTI through 150 days after injection was 78.4% (95% CI: 51.9–90.3%) at 29–34 weeks gestation and 76.8% (95% CI: 49.4–89.4%) at ≥ 35 weeks gestation. Early real-world data from northern hemisphere countries in the 2023–2024 winter suggest high protective effectiveness of up to 90% against hospitalisation among infants aged < 6 months, with universal funded immunisation able to achieve coverage rates of > 90% in newborn infants.[33–36]

Vaccines for older adults

There are currently two RSV protein subunit (pre-fusion F protein) vaccines (Abrysvo [Pfizer]; Arexvy [GSK]) and one mRNA vaccine (mRESVIA [Moderna]) registered by the TGA for the prevention of RSV-associated LRTI in people aged ≥ 60 years. Table 4 summarises the key efficacy and safety data of Abrysvo, Arexvy and mRESVIA from some ongoing clinical trials.

Efficacy

The efficacy of a single dose of RSV vaccine in preventing laboratory-confirmed RSV-associated LRTI among adults aged ≥ 60 years was similar in the respective clinical trials of Arexvy (82.6% [96.95% CI: 57.9–94.1%]) and Abrysvo (88.9% [95% CI: 53.6–98.7%]) over one RSV season. Efficacy appeared lower at 61.1% (95% CI: 34.7–76.8%) for mRESVIA (Table 4). Protective efficacy in the second season following a single dose of Abrysvo and Arexvy given in the first season was 78% and 56%, respectively. Overall efficacy of a single dose in preventing RSV-associated LRTI over two seasons in older adults aged ≥ 60 years was 82% for Abrysvo and 79% for Arexvy. Data to a median of 18.8 months follow-up for mRESVIA shows vaccine efficacy to wane to 49.9%.[37]

The efficacy of a single dose of Arexvy against severe RSV-associated LRTI (defined on the basis of clinical assessment by the investigator; lower respiratory tract signs; and/or need for respiratory support) was 94% during the first season and 64% during the second season, with the combined efficacy over two seasons of 79%. The efficacy of a single dose of Abrysvo against severe RSV-associated LRTI was also evaluated in a clinical trial; however, the evidence was of low certainty due to insufficient episodes of severe disease. Severe RSV was not a measured outcome in the mRESVIA trial.

Respective studies of co-administration of Arexvy, Abrysvo and mRESVIA with influenza vaccines generally show predefined non-inferiority immunogenicity criteria for all vaccines being met. Despite this, co-administration studies demonstrated slightly lower immune responses to certain strains contained in the RSV vaccine and influenza vaccines compared to when they are administered separately.[38-40] While these decreases were relatively minor, the impact on protection from RSV and influenza vaccines is uncertain. The benefits of co-administration in allowing a patient to receive all necessary vaccines at one visit may likely outweigh such concerns.

Safety

Overall, a higher proportion of RSV vaccine recipients in clinical trials experienced local and systemic AEs within 4–7 days following vaccination. Common local AEs, including pain, swelling, and redness at the injection site, were reported by 12% of Abrysvo recipients and by approximately 60% of Arexvy or mRESVIA recipients, compared to 7–16 % who received placebo (Table 4). Common systemic AEs were fatigue, headache, and myalgia. Systemic AEs were reported in 28% of Abrysvo recipients and approximately 50% of people who received either Arexvy or mRESVIA, compared to 23–33% of those who received a placebo. For serious AEs, no significant differences were seen between vaccine and placebo groups across the three respective phase 3 vaccine clinical trials.

During the clinical trials for these vaccines, adverse events of special interest (AESI), including autoimmune inflammatory neurologic conditions (e.g. Guillain-Barré Syndrome [GBS]) and atrial fibrillation, were also reported. However, the number of these AESI were very small and not unbalanced between study arms, precluding any possibility of establishing a causative link with RSV vaccines. In the USA, a preliminary analysis of first season post-marketing safety surveillance data has suggested a higher incidence of GBS than expected, in the six weeks after vaccination with Abrysvo or Arexvy, of approximately 6–9 per 1 million doses.[41] However, GBS remains rare, and further confirmatory analyses are required once larger numbers of people have been vaccinated to determine whether the observed association exists.

Table 4: Respiratory syncytial virus (RSV) vaccines for older adults: target age groups and highlights of efficacy, and safety data of Abrysvo, Arexvy, and mRESVIA from pivotal studies, as of April 2025

Category	Abrysvo	Arexvy	mRESVIA
References	42–44	45, 46	37, 47
Registered age	≥ 60 years	≥ 50 years	≥ 60 years
Age groups recommended for vaccination by ATAGI[a]	• 75 years: all adults • 60–74 years: First Nations people and individuals with medical conditions that increase risk	• ≥ 75 years: all adults • 60–74 years: First Nations people and individuals with medical conditions that increase risk	Recommendations pending: awaiting ATAGI evaluation
Age groups that can consider vaccination	60–74 years: individuals with no medical conditions that increase risk	• 60–74 years: individuals with no medical conditions that increase risk • 50–59 years: individuals with medical conditions that increase risk	Awaiting ATAGI evaluation
Vaccine description	Recombinant bivalent (RSV A and RSV B) RSV Prefusion F glycoprotein vaccine	Recombinant RSV Prefusion F glycoprotein vaccine adjuvanted with adjuvanted with AS01E	Lipid nanoparticle–encapsulated mRNA based vaccine encoding the RSV A derived prefusion F glycoprotein
Definition of RSV-associated LRTI[b]	Laboratory confirmed RSV-associated LRTI with ≥ 3 signs/symptoms	Laboratory confirmed RSV-associated LRTI with ≥ 2 lower respiratory signs/symptoms including at least 1 respiratory sign or ≥ 3 lower respiratory symptoms	Laboratory confirmed RSV-associated LRTI with ≥ 3 lower respiratory signs/ symptoms
Follow-up duration in months	Mean[43] • Season 1: 7.1 • Season 2: 7.6 Over two seasons: 17.6	Median (interquartile range, IQR)[46] • Season 1: 6.7 (5·7–7·8) • Season 2: 6.3 (5·7–6·8) • Season 3: 7.0 (7·0–7·0) Over three seasons: 30.6 (26·2–32·0)	Median (range)[37,47] • Primary analysis: 3.7 (0.5–12.6) • Additional analysis: 8.6 (0.5–17.7) • March 2024 analysis: 18.8 (0.5–24.0)
Efficacy among adults aged ≥ 60 years[b,c,d]	First season[43] • RSV LRTI: 88.9% (95% CI: 53.6–98.7) Second season[44,e] • RSV LRTI: 77.8% (95% CI: 51.4– 91.1) Combined two seasons[44,f] • RSV LRTI: 81.5% (95% CI: 63.3–91.6)	First season[45] • RSV LRTI: 82.6% (96.95% CI: 57.9–94.1); severe RSV LRTI: 94.1% (96.95% CI: 62.4–99.9) Second season[45,e] • RSV LRTI: 56.1% (95% CI: 28.2–74.4); severe RSV LRTI: 64.2% (95% CI: 6.2–89.2) Third season[46,e] • RSV LRTI: 48.0% (95% CI: 8.7–72.0); severe RSV LRTI: 43.3% (95% CI: -45.3–81.3) Combined three seasons[46,f] • RSV LRTI: 62.9% (97.5% CI: 46.7–74.8); severe RSV LRTI: 67.4% (95% CI: 42.4–82.7)	Primary analysis period[47] • RSV LRTI: 80.9% (95.1% CI: 50.1–92.7) Additional analysis period[47] • RSV LRTI: 61.1% (95% CI: 34.7–76.8) March 2024 analysis period[37] • RSV LRTI: 49.9% (95% CI: 27.8–65.6)

Category	Abrysvo	Arexvy	mRESVIA
Local AE[d,g]	Local AEs within 7 days of vaccination were experienced by 12.1% (95% CI: 11.1–13.3) of vaccine recipients compared with 6.6% (95% CI: 5.8–7.5) of placebo recipients[42]	Local AEs within 4 days of vaccination were experienced in 62.2% of vaccine recipients compared with 10.0% placebo recipients; pain was the most common reaction and reported by 60.9% vaccine recipients and 9.3% of placebo recipients[45]	Injection site symptoms within 7 days of vaccination included pain, axillary swelling or tenderness, swelling, and redness, and were reported by 55.9% of vaccine recipients and 13.8% of placebo recipients[47]
Systemic AE[g]	27% of vaccine recipients experienced systemic AEs compared with 26% placebo recipients; common systemic adverse events include fatigue, headache, and myalgia[42]	49.4% of vaccine recipients experienced systemic AEs compared with 23.2% of placebo recipients; fatigue was the most common and reported by 33.6% of vaccine recipients compared with 16.1% of placebo recipients[45]	Systemic AEs were experienced by 30.8% of vaccine recipients compared to 20.0% placebo recipients; common systemic AEs were fatigue, headache, and myalgia[47]
Serious AE[g]	No difference in the rates of serious adverse events compared to placebo.	No difference in the rates of serious adverse events compared to placebo.	No difference in the rates of serious adverse events compared to placebo.

a ATAGI: Australian Technical Advisory Group on Immunisation.

b LRTI: lower respiratory tract infection.

c Evidence for efficacy of Abrysvo against severe RSV LRTI (not shown) is of low certainty due to insufficient data.

d CI: confidence interval.

e Season two or three efficacy of a single dose given in the first season.

f Efficacy of a single dose over two or three RSV seasons.

g AE: adverse event.

Current RSV immunisation programs and target populations in Australia and comparative countries

Australia

Since late 2023, three new RSV vaccines and a monoclonal antibody (nirsevimab) have been registered in Australia. Jurisdictional immunisation programs using nirsevimab were introduced in the Australian Capital Territory, New South Wales, Queensland, Tasmania and Western Australia in early 2024, with varying eligibility.[48–52] In Australia, a national RSV maternal and infant immunisation program commenced in early 2025, targeting infant protection through maternal vaccination in pregnancy funded under the NIP. This has been coordinated with state and territory funding of nirsevimab for infants and children requiring protection between the ages of birth and 2 years of age. Legislative change under consideration may eventually allow funding of nirsevimab on the NIP.

An RSV vaccine for older adults (Abrysvo) received a positive recommendation for adults aged ≥ 75 years, and for First Nations people aged 60 to 74 years, in November 2024 by the Pharmaceutical Benefits Advisory Committee (PBAC), potentially allowing for its inclusion on the NIP in the future.[53] Arexvy is being reconsidered by PBAC for inclusion on the NIP in July 2025 after a previous negative recommendation in July 2024.

ATAGI has provided recommendations for the use of RSV vaccines and nirsevimab via statements[54,55] and the Australian Immunisation Handbook.[3] ATAGI will update the recommendations, including those on mRESVIA once it is available for use.

Protection of infants by maternal vaccination or monoclonal antibodies

One RSV vaccine, Abrysvo, is registered for administration in pregnant persons at 24–36 weeks to protect newborns and infants against RSV-associated LRTI. ATAGI currently recommends a single dose of Abrysvo among pregnant people at 28–36 weeks of gestation at any time of the year. The narrower recommended dosing window during pregnancy takes into consideration current uncertainty around the potential increased risk of preterm birth after vaccination, while ensuring enough opportunities for timely vaccination of pregnant persons at routine antenatal appointments and maximising protection should an infant be born preterm.

The lower gestational age limit may be reduced in future if surveillance of post-licensure use in pregnancy indicates absence of any association between RSV vaccination and preterm birth.

Abrysvo can be given beyond 36 weeks gestation; however, if given less than two weeks before delivery, the newborn infant will not be adequately protected by maternal vaccination, due to the limited time available for transplacental transfer of vaccine-induced maternal antibodies. Protection from maternal RSV vaccination may also be suboptimal due to impaired maternal response to vaccination during pregnancy (e.g. severe maternal immunosuppression) or if an infant undergoes procedures such as exchange transfusion, cardiopulmonary bypass or extracorporeal membrane oxygenation which can be associated with loss of protective RSV antibodies. In these situations, the administration of a long-acting RSV monoclonal antibody such as nirsevimab can be considered for additional prophylaxis. Nirsevimab may also be considered irrespective of maternal RSV vaccination in infants at increased risk of severe RSV disease, and for medically at-risk children who enter their second RSV season.[3]

A long-acting RSV monoclonal antibody for infants, nirsevimab, can also be considered as an alternative to maternal RSV vaccine. In Australia, it is being used to complement maternal vaccination as a second opportunity to provide protection to infants, particularly those born to mothers who did not receive the RSV vaccine during pregnancy at least two weeks before giving birth.

Protection of older adults

ATAGI recommends a single dose of RSV vaccine in all adults aged ≥ 75 years. ATAGI also recommends RSV vaccinations in adults aged 60–74 years who are at increased risk of severe RSV disease, specifically First Nations people and individuals with specified medical conditions (Table 5). Individuals aged 50–59 years of age, and at increased risk of severe RSV disease, can consider vaccination with Arexvy. The list of medical conditions recommended for RSV vaccination broadly aligns with the conditions recommended for vaccination for other acute respiratory virus diseases (influenza and COVID-19) based on evidence and expert opinion. There are relatively less data showing direct associations between severe RSV disease and some specified medical conditions (e.g. some chronic metabolic disorders, liver disorders and neurological conditions); however, these are included based on first principles.

RSV vaccination may also be considered in healthy adults aged 60–74 years. However, the benefits are expected to be less, due to a comparatively lower risk for severe RSV disease than in people aged ≥ 75 years or in those with risk conditions for severe RSV. RSV vaccines can be given at any time of the year, but where possible should be offered prior to the start of the RSV season. There is no preferential recommendation for a specific brand of the registered vaccines in this age group; however, at the time of publication, mRESVIA is not yet available for prescription.

Table 5: Medical conditions with increased risk of severe respiratory syncytial virus (RSV) disease recommended by the Australian Technical Advisory Group on Immunisation (ATAGI) for RSV vaccination among older adults

Risk category	Example medical conditions[a]
Cardiac disease	Congenital heart disease, congestive heart failure, coronary artery disease
Chronic respiratory conditions	Suppurative lung disease, bronchiectasis, cystic fibrosis, chronic obstructive pulmonary disease, chronic emphysema, severe asthma (requiring frequent medical consultations or the use of multiple medicines)
Immunocompromising conditions	HIV infection, malignancy, immunocompromise due to disease or treatment, asplenia or splenic dysfunction, solid organ transplant, haematopoietic stem cell transplant, CAR T-Cell therapy[b]
Chronic metabolic disorders	Type 1 or type 2 diabetes, amino acid disorders, carbohydrate disorders, cholesterol biosynthesis disorders, fatty acid oxidation defects, mitochondrial disorders, organic acid disorders, urea cycle disorders, vitamin/cofactor disorders, porphyrias
Chronic kidney disease stage 4 or 5	Chronic renal impairment – eGFR < 30 mL/min (stage 4 or 5)[c]
Chronic neurological conditions	Hereditary and degenerative CNS diseases, seizure disorders, spinal cord injuries, neuromuscular disorders, conditions which increase respiratory infection risk[d]
Chronic liver disease	Advanced liver disease
Obesity	Body mass index ≥ 30 kg m^{-2}

a These examples are not exhaustive, and providers may include individuals with conditions similar to those listed above based on their clinical judgement.

b HIV: human immunodeficiency virus; CAR: chimeric antigen receptor.

c eGFR: estimated glomerular filtration rate.

d CNS: central nervous system.

Current RSV immunisation recommendations in other countries

The main differences between the ATAGI recommendations in Australia and those in other countries relates to registration and availability of immunisation products. The USA is one of the few countries that currently has availability of RSV vaccines for older adults and pregnant women as well as nirsevimab for infants. Differences exist in the timing of administration of RSV vaccination during pregnancy, the infant populations recommended for receiving monoclonal antibodies, and the age groups and strength of the recommendation to receive RSV vaccines among older adults (Table 6). The UK and Canada have provided recommendations for prevention of RSV during 2024–2025 in both older adults and infants with implementation of national or provincial funded programs.[56–58] Spain implemented a program of passive immunisation for all infants from birth from the 2023–2024 RSV season.[59]

Use of RSV vaccine during pregnancy and monoclonal antibody among infants

In the USA, the Advisory Committee on Immunization Practices (ACIP) has developed clinical guidance on the administration of both maternal vaccination during pregnancy and nirsevimab after birth to prevent RSV-associated LRTI in infants. ACIP recommends the seasonal administration (in September–January) of RSV vaccine in pregnant persons at 32–36 weeks.[60] The narrower dosing window compared to the clinical trial dosing interval (of 24-36 weeks) was due to the concern relating to the potential increased risk of preterm births. The difference in observed risk of preterm births was less with this restricted dosing window of administration (4.2% [68/1,628] in vaccine group vs 3.7% [59/1,604] in placebo group; RR: 1.15 [95% CI: 0.82–1.61]); however, the certainty of association of RSV vaccination with preterm birth remains very low.[23,61,62] Seasonal vaccination and a smaller gestational window for administration are balanced by ACIP's recommendation for routine administration of nirsevimab in all infants aged < 8 months, born during or entering their first RSV season, whose mother did not receive RSV vaccine in pregnancy, has unknown vaccination status, or who were born within 14 days of maternal vaccination. This would include all babies born prior to 34 weeks gestation.[60]

ACIP also recommends nirsevimab for young children aged 8–19 months at increased risk for severe RSV disease and entering their second RSV season.

The Joint Committee on Vaccination and Immunisation (JCVI) in the UK has provided broad advice on potential RSV immunisation strategies, taking into account relevant cost-effectiveness modelling.[63,64] A national program of maternal RSV immunisation was commenced in September 2024 for all pregnant women from 28 weeks' gestation in the UK.[65] Nirsevimab is recommended for certain high risk children.[58] Canada's National Advisory Committee on Immunization (NACI) has recommended an initial infant program, preferentially using nirsevimab over maternal RSV vaccine, targeted at infants with increased risk of severe disease in their first or second season. It has subsequently recommended that nirsevimab be considered for any infant less than 8 months of age entering, or born during, their first RSV season.[56] Spain implemented a funded nirsevimab program for all children under 6 months of age from the 2023–2024 season to be given at birth for those born during the RSV season or at the beginning of the RSV season if born outside of the RSV season.[66]

Use of RSV vaccines in older adults

In the USA, ACIP initially recommended RSV vaccination in all older adults aged ≥ 60 years using shared clinical decision-making based on the potential for benefits.[67] Subsequently, this was updated in June 2024 to all adults aged ≥ 75 years and adults aged 60–74 years who are at increased risk for severe RSV disease, to facilitate easier decision-making for providers.[68] This recommendation now aligns closely with ATAGI's recommendation in the Australian setting.

The UK's JCVI currently recommends RSV vaccination in older adults aged ≥ 75 years. A nationally funded program commenced in September 2024 for all adults turning 75 years of age, with a one-off single year catch up program for those aged 75–79 years inclusive.[69]

Table 6: Recommendations and advice in the United States of America (USA) and the United Kingdom (UK), as of January 2025

Life stage protected	Immunisation method	USA[a]	UK[b]
Infants	Maternal vaccine	• 32–36 weeks gestation • Seasonal program (i.e. September–January)	All pregnant women from 28 weeks' gestation
	Monoclonal antibody (nirsevimab)	• All infants born at < 34 weeks gestation • Infants aged < 8 months born during or entering their first RSV season whose mother did not receive RSV vaccine, whose mother's receipt of RSV vaccine is unknown, or who were born < 14 days after maternal vaccination • Young children aged 8–19 months at increased risk for severe RSV disease and entering their second RSV season regardless of maternal RSV vaccination	• For the selective immunisation of high-risk infants and children • Usually in or from around calendar week 40 in early October • Eligible conditions include chronic lung disease of prematurity (CLD), congenital heart disease (CHD), Severe Combined Immunodeficiency Syndrome (SCID). Also dependent on gestational age at birth for some categories
	RSV vaccine and nirsevimab	Administration of both products is not needed for most infants; however, based on the clinical judgment of the healthcare provider, nirsevimab may be considered for infants born to vaccinated mothers in rare circumstances (e.g. mothers with immunocompromising condition, infants with loss of maternal antibodies)	–
Older adults	RSV vaccine	• Adults aged ≥ 75 years • Adults aged 60–74 years who are at increased risk for severe RSV disease • Vaccination optimally before the onset of the RSV season	• Adults turning 75 years of age • Catch up for those aged 75–79 years until August 2025

a Recommendations/advice as sourced from references 60 and 68.

b Recommendations/advice as sourced from reference 63.

Anticipated issues and information gaps/needs

Need for robust data on the disease burden in older adults

Current estimates on the RSV disease burden in Australian adults is predominantly derived from health administrative data (AIHW NHMD) identifying relevant RSV hospitalisations based on selected ICD codes. This approach will likely underestimate the true RSV disease burden. Variations in the propensity for clinical testing of people with acute respiratory disease across different healthcare services or settings, and over time, also contribute to variable underestimation and are hard to assess. Additional limitations of the available hospitalisation data include the inability, due to data aggregation, to accurately assess disease burden among medically at-risk populations, and among older First Nations adults aged ≥ 65 years, by specific narrower age bands. The utility of laboratory-confirmed RSV data from the NNDSS is impacted by constraints such as potential variability in testing patterns, incomplete identification of First Nations people and of death as an outcome (noting that most cases are not followed to outcome status for surveillance purposes).

Alternative methodological approaches to account for under-ascertainment of RSV cases, such as statistical modelling and/or the application of an adjustment factor, may improve reliability of disease burden estimates, especially for adults. Additionally, better quality data about specific populations, particularly First Nations people and medically at-risk individuals, are also needed. Such robust data may be acquired by data linkage with readily available datasets or by the implementation of sentinel active case ascertainment through hospital surveillance with laboratory-confirmed RSV, such as via the Influenza Complications Alert Network (FluCAN) and Paediatric Active Enhanced Disease Surveillance (PAEDS). The Australian National Surveillance Plan for COVID-19, Influenza, and RSV,[70] published in April 2024, describes the approach to more comprehensive surveillance of RSV disease in addition to influenza and COVID-19 in Australia.

Need for strengthened disease and safety surveillance and program monitoring

Data linkage will also provide key assets to use for monitoring and assessment of the effectiveness of these RSV prevention strategies and their impact on reducing the disease burden. Well-conducted analyses using this approach can also assist assessments of the safety of RSV vaccines or monoclonal antibodies, including the monitoring of AESI (e.g. inflammatory neurologic events in adults, premature births and other pregnancy outcomes), which clinical trials are not adequately powered to detect. Additionally, any potential inequities in access to or uptake of RSV immunisation products, and in health outcomes following the implementation of an upcoming national program, will need to be carefully evaluated and addressed as they occur.

Monitoring immunisation coverage

Until recently, nationally representative data on maternal vaccine uptake among pregnant people were lacking, with the best sources of data coming from a limited number of jurisdictional perinatal data collection analyses.[71] As part of recent changes to the Australian Immunisation Registry (AIR), a field indicating whether vaccination occurred during pregnancy, and the potential to record administration of nirsevimab, were introduced in March 2024 and further refined, based on provider feedback, in December 2024.[72,73] This new functionality is aimed at ensuring there are effective strategies to conduct timely monitoring of RSV vaccine uptake in pregnancy alongside coverage of other antenatal vaccines. However, the AIR is still unable to record key data elements such as gestational age, or to adequately link mother-infant pairs, and consistent data entry by vaccination providers will be essential. Linked datasets are likely to be critical to allowing assessment of the safety and effectiveness of maternal RSV vaccination or nirsevimab on infant RSV disease and to aid in informing the relative merits of these strategies, particularly for protecting infants at increased risk of severe RSV disease.

There are existing challenges in monitoring vaccine uptake among other at-risk populations, such as people with medical conditions and First Nations people, due to the inability to identify all these at-risk individuals on the AIR. Hence, building capacity to link the AIR to other databases that include health outcome data are needed to identify populations at increased risk of poor health outcomes, to evaluate RSV and other vaccine coverage, and to assess vaccine program impact.

Other future considerations for RSV immunisation

The Australian Immunisation Handbook recommends a single dose of RSV vaccine in older adults, with no current recommendations for further doses, due to absence of clinical data on their incremental benefits and/or safety. For pregnant people who have received their first RSV vaccine dose, data on antibody persistence over time are still needed. Data are also awaited on the immunogenicity, safety and clinical effectiveness of repeat vaccination, in subsequent pregnancies, against severe infant RSV infection.

Regarding older adults, real-world evidence confirming the effectiveness of a single dose of RSV vaccine is required, as well as data on the duration of protection beyond the third season as shown in clinical trials. If a program of periodic RSV re-vaccination is contemplated and offered seasonally, its potential impact on uptake of the influenza and COVID-19 vaccines, which involve annual seasonal programmatic delivery, needs to be considered. Combination vaccines for RSV and other acute respiratory illnesses (e.g. influenza and COVID-19) in older adults are currently in the pipeline; the future availability of these could simplify immunisation practices and optimise uptake, leading to improved control of several acute respiratory viruses which cause significant respiratory morbidity and mortality in older adults each year.

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