Decision making in vaccine policy

An overview of how Australian vaccine recommendations are developed

Allen Cheng, Katie Flanagan & Michelle Giles
28 August 2025

Ms Amanda Van Eldik, NCIRS

NCIRS National Centre for Immunisation Research and Surveillance Australia

A1. Opening quiz

B1 Developing vaccine clinical recommendations – an RSV case study

B2.1 Who should be vaccinated?

B2.2 When should you immunise each population?

B2.3 Is there a preference for a particular program or product?

Developing vaccine clinical recommendations

An RSV case study

Note

The following slides have been developed for educational purposes only. They are not intended to demonstrate how ATAGI developed the current RSV program but model some scenarios for discussion on how such policy decisions are made.

Scenario: You are on ATAGI and two new RSV immunisation products have been registered by the TGA in Australia for the protection of infants

RSV monoclonal antibody for infants – Beyfortus

Beyfortus for infants provides passive immunisation for prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV) in infants and young children via **monoclonal antibodies.**

Season 1 = 50mg (<5kg); 100mg (≥5kg)

Season 2 = 200mg

RSV maternal vaccine - Abrysvo

The Abrysvo maternal vaccine provides passive immunisation for prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV) in infants via **active immunisation of pregnant women** (maternal vaccination).

Plenary discussion (7 mins)

To develop the clinical advice for Australian immunisation providers what information would you want to know as an ATAGI member?

To develop the clinical advice for Australian immunisation providers what information would you want to know as an ATAGI member?

Safety data

Is the immunisation product well-tolerated? Are there any potential safety signals?

Efficacy data

Duration of protection, comparison to other available products

Disease burden

Epidemiology, seasonality – add equity after this point

Equity

What is the potential impact of the immunisation product on health inequalities between populations?

Perception of risk

Do the public and immunisation providers consider this disease of significant risk?

TGA status

Is it registered and for what ages and/or sub-populations

Funding

NIP, non-NIP or private market

Other NITAGs

What are other countries technical advisory groups recommending?

Special populations

High-risk populations, e.g. immunocompromised, pregnant patients

Who should be vaccinated?

Who would you recommend vaccination for? and in the context of limited supply who would you prioritise and why?

Key information to consider:

- Age-registration
- Epidemiology of RSV in infants and children *(EtR domain: is this problem a priority?)*
  - All infants and children aged less than 5 years
  - Infants and children with medical risk conditions
  - Aboriginal and Torres Strait Islander infants and children

TGA registered cohorts

RSV maternal vaccine - Abrysvo

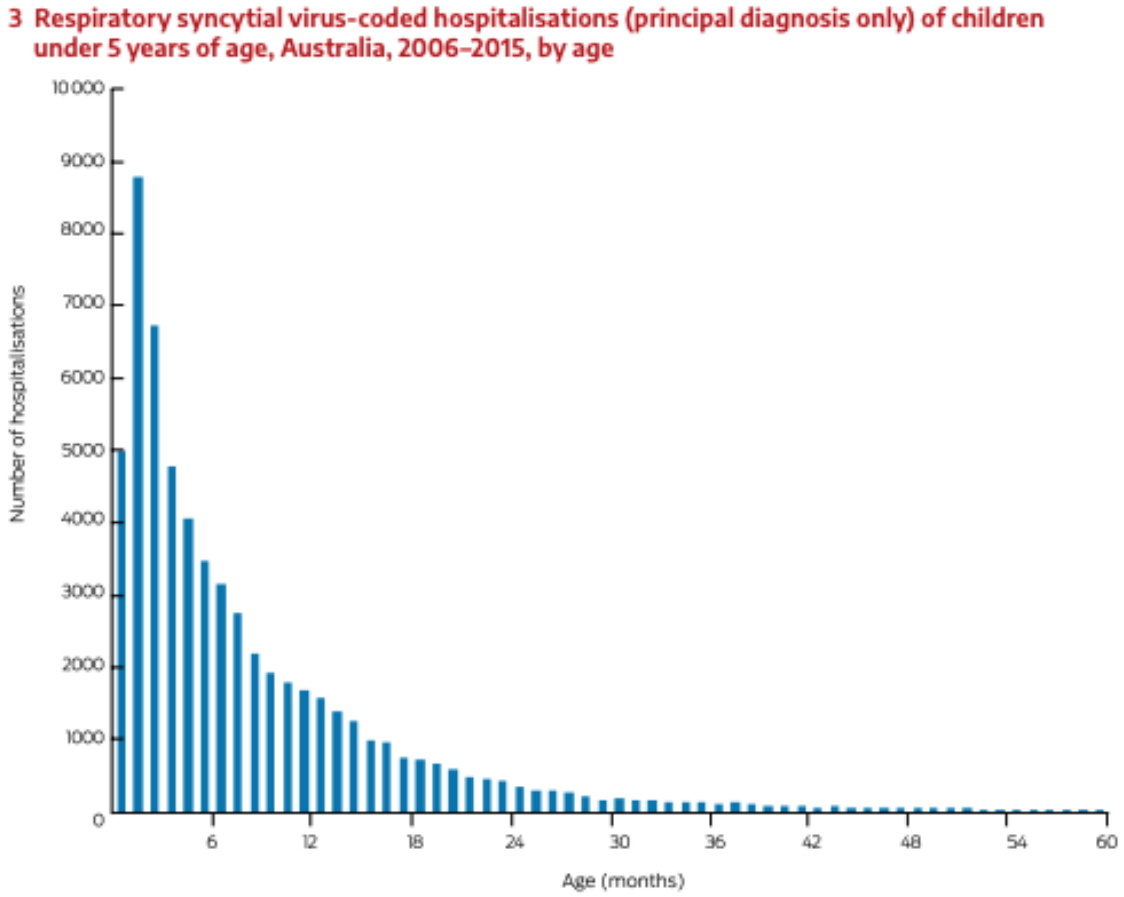
Pregnant women between 24-36 weeks of gestation

RSV monoclonal antibody – Beyfortus (Nirsevimab)

- Neonates and infants born during or entering their first RSV season.
- Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season

Epidemiology of RSV disease: hospitalisations in children

Rate of hospitalisations in children aged ≤5 years from the AIHW National Hospital Morbidity Database



Between 2006–2015, hospitalisations from RSV in children under 5 years of age were greatest in those aged less than 6 months and peaked in children aged 1 month.

Source: Saravanos et al (2019)

Epidemiology of RSV disease: hospitalisations

Rate of hospitalisations in Aboriginal and Torres Strait Islander peoples from the AIHW National Hospital Morbidity Database

4 Respiratory syncytial virus-coded hospitalisations (principal diagnosis only) of Indigenous and non-Indigenous Australians, 2011–2015, by age group

	Indigenous Australians		Non-Indigenous Australians		
Age group	Number	Rate* (per 100 000 population)	Number	Rate* (per 100 000 population)	Incidence rate ratio (95% CI)
Total number	3395	97	32 629	29	3.3 (3.2–3.5)
< 6 months	1851 (54.5%)	4310	16 155 (49.5%)	2253	1.9 (1.8–2.0)
< 5 years	3310 (97.5%)	789	30 063 (92.1%)	420	1.8 (1.8–2.0)
0–2 months	1003 (29.5%)	4671	10 364 (31.8%)	2890	1.6 (1.5–1.7)
3–5 months	848 (25.0%)	3949	5791 (17.7%)	1615	2.5 (2.3–2.6)
6–11 months	805 (23.7%)	1875	6386 (19.6%)	891	2.1 (2.0–2.3)
12–23 months	497 (14.6%)	589	5323 (16.3%)	371	1.6 (1.4–1.7)
24–59 months	157 (4.6%)	63	2199 (6.7%)	51	1.2 (1.1–1.5)
5–14 years	22 (0.6%)	3	311 (1.0%)	2	1.2 (0.7–1.8)
15–24 years	7 (0.2%)	1	58 (0.2%)	< 0.5	2.5 (1.0–5.6)
25–34 years	4 (0.1%)	1	70 (0.2%)	< 0.5	1.9 (0.5–5.1)
35–44 years	9 (0.3%)	2	120 (0.4%)	1	2.9 (1.3–5.6)
45–54 years	16 (0.5%)	5	170 (0.5%)	1	4.3 (2.4–7.1)
55–64 years	10 (0.3%)	5	317 (1.0%)	2	2.0 (1.0–3.7)
≥ 65 years	17 (0.5%)	8	1520 (4.7%)	9	0.9 (0.5–1.4)

CI = confidence interval. * Denominator based on Australian Bureau of Statistics census data. ◆

Between 2011–2015, hospitalisations from RSV in Aboriginal and Torres Strait Islander children under 5 years of age were greatest in those aged less than 6 months and peaked in children aged 0–2 months.

The rate of hospitalisations is higher in Aboriginal and Torres Strait Islander children than non-Indigenous children, with an IRR of 1.9 for children aged less than 6 months.

Source: Saravanos et al (2019)

Epidemiology of RSV disease: infant priority populations

Children with medical risk conditions

National data sources are not available to provide rates of RSV disease/hospitalisations for children with medical risk conditions

Other sources of information will be required to guide decision on medical risk priority groups, such as:

- Other NITAGs
- Available literature
- Criteria for palivizumab (an RSV-specific monoclonal antibody that has been used for certain medically at-risk children since 1999)

Infant priority populations

Other NITAG - ACIP

- Nirsevimab is recommended for 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
- Nirsevimab may be considered for infants born to vaccinated mothers in rare circumstances when, based on the clinical judgment of the health care provider, the potential incremental benefit of administration is warranted†
- Nirsevimab is recommended for infants and children aged 8–19 months at increased risk of severe RSV disease and entering their second RSV season, regardless of maternal RSV vaccination‡

†For example, infants born to mothers who might have not mounted an adequate immune response to RSV vaccination (such as persons with immunocompromising conditions) or who have conditions associated with reduced transplacental antibody transfer (such as persons with HIV infection); infants who might have experienced a loss of maternal antibodies, such as those who have undergone cardiopulmonary bypass or extracorporeal membrane oxygenation; and infants with substantially increased risk for severe RSV disease, such as those with hemodynamically significant congenital heart disease, or intensive care admission requiring oxygen at hospital discharge

‡Infants and children at increased risk of severe disease who are recommended to receive nirsevimab when entering their second RSV season include: Children with chronic lung disease of prematurity who required medical support (chronic corticosteroid therapy, bronchodilator therapy, or supplemental oxygen) any time during the 6-month period before the start of the RSV season; children with severe immunocompromise; children with cystic fibrosis who have either 1) manifestations of severe lung disease (previous hospitalisation for pulmonary exacerbation in the first year of life or abnormalities in chest imaging that persist when stable) or 2) weight-for-length <10th percentile; and American Indian or Alaska Native children

Source: Fleming-Dutra KE, et al. 2023

Infant priority populations

Literature – Shi et al (2022), *Risk Factors for Poor Outcome or Death in Young Children With Respiratory Syncytial Virus–Associated Acute Lower Respiratory Tract Infection: A Systematic Review and Meta-Analysis*

Table 1. Meta-analyses of Risk Factors for Poor Outcome in Children With Respiratory Syncytial Virus–Associated Acute Lower Respiratory Tract Infection

	Studies Using Multivariable Analysis			Studies Using Univariable Analysis		
Risk Factor	Studies, No.	OR (95% CI)	I^2 Statistic, %	Studies, No.	OR (95% CI)	I^2 Statistic, %
Any comorbid condition	5	2.69 (1.89–3.83)	0.0	5	3.21 (1.97–5.24)	73.2
Chronic lung disease	3	3.20 (0.97–10.57)	79.8	5	4.17 (0.78–22.21)	96.9
Congenital heart disease	6	3.40 (2.14–5.40)	64.1	8	4.84 (3.16–7.42)	73.8
Down syndrome	2	NA		3	2.29 (0.91–5.76)	67.9
Prematurity						
GA <37 wk	6	1.75 (1.31–2.36)	61.5	9	2.73 (1.92–3.87)	81.4
GA ≤32 wk	3	2.68 (1.43–5.04)	46.7	3	5.90 (2.35–14.83)	92.2
Coinfection	2	NA		3	3.11 (0.56–17.27)	94.4
Sex (male)	5	1.39 (0.95–2.04)	44.7	7	1.13 (0.95–1.35)	41.5
Age						
<3 mo	2	NA		4	4.91 (1.64–14.71)	82.0
<6 mo	3	2.02 (1.73–2.35)	0.0	3	2.15 (1.34–3.46)	63.9

Abbreviations: CI, confidence interval; GA, gestational age; NA, not available; OR, odds ratio.

Infant priority populations

Palivizumab criteria

For immunoprophylaxis against severe Respiratory Syncytial Virus (RSV) lower respiratory tract infections in high-risk infants during months of increased incidence of the virus. High-risk infants include:

- Ex-preterm infants with chronic lung disease (oxygen or respiratory support at 36 weeks post menstrual age)
- Preterm infants born ≤26 weeks gestation
- All indigenous neonates born ≤28 weeks gestational
- Infants with haemodynamically significant congenital heart disease between 0 to <6 months age
- Neonates having undergone a major surgical procedure and requiring prolonged hospitalisation
- Infants at risk of severe RSV bronchiolitis including infants with moderate to severe pulmonary conditions particularly those requiring continued respiratory and/or oxygen support.
- Children with severe pulmonary abnormality or neuromuscular disease that impairs the ability to clear secretions from the upper airways may be considered for prophylaxis in the first year of life.
- Children younger than 24 months who will be profoundly immunocompromised during the RSV season may be considered for prophylaxis.

Source: adapted from QLD and WA hospital criteria for palivizumab (noting no national criteria)

Discussion

Packet labelled B2.1

In groups of 2-3 – 10 minutes to review the data and answer the following questions:

1. If there was a limited supply of Beyfortus, which groups would you prioritise? Considering,
   a) Would you give it to infant's whose mother had received the maternal vaccine?
   b) Would you prioritise any second season medical risk children over any first season children? (noting required dose for 2nd season children is 4 times the dose for infants)
2. If both Abrysvo AND Beyfortus were available, what would you recommend?

Plenary discussion – 6 minutes:

1. If there is consensus, do the Vaccine Presidents sign-off on the recommendations?
2. If there is no consensus, what is the proposal from the Vaccine Presidents?

What did ATAGI decide?

Identified risk conditions for severe disease

Box 1: Risk conditions for severe RSV disease in infants and young children

- Prematurity (particularly infants born <32 weeks gestational age)[10,11]
- Haemodynamically significant congenital heart disease[9-11]
- Significant immunosuppression, e.g. due to solid organ transplant, haematopoietic stem cell transplant,[12] or primary immune deficiencies such as severe combined immunodeficiency (SCID)[9,10]
- Chronic lung disease that requires oxygen or respiratory support beyond 36 weeks gestation or at hospital discharge[9,10]
- Neurological conditions that impair respiratory function[10]
- Cystic fibrosis with severe lung disease or weight for length <10th percentile[10]
- Trisomy 21 or other genetic conditions that increase the risk of RSV[13]

Risk group prioritisation

Table 1: Risk of severe RSV disease by age, prematurity and medical risk conditions

Age	Healthy	Prematurity (32 to <37 weeks gestation)	Risk condition listed in Box 1 (includes prematurity <32 weeks gestation)
Birth to <6 months*	Moderate risk	Moderate risk	High risk
6 to <12 months	Low risk	Low-Moderate risk	Moderate risk
12 to 24 months	Low risk. Nirsevimab not recommended	Low risk. Nirsevimab not recommended	Moderate risk

*Risk is particularly increased in infants aged 0 to <3 months.

What did ATAGI decide?

ATAGI's recommendations

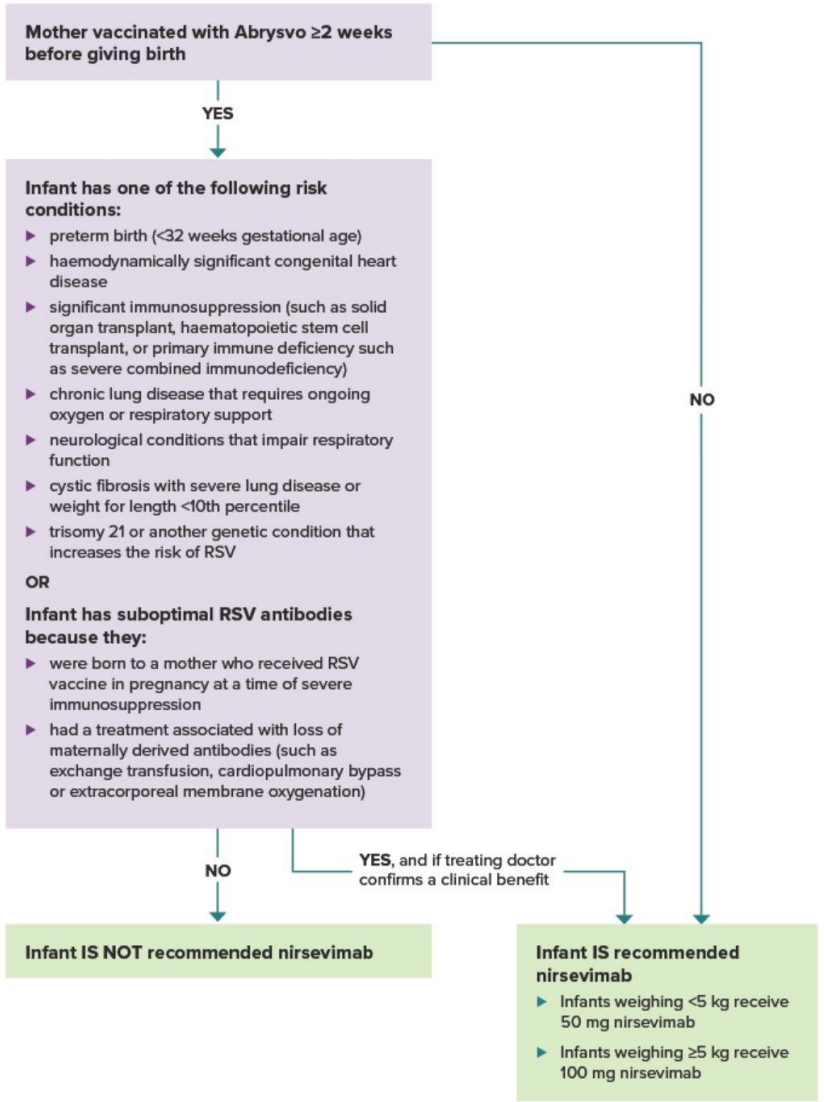
ATAGI recommended both RSV immunisation products.

Abrysvo was recommended for all pregnant women

Beyfortus was recommended for:

- Infants born to mother's who did not receive Abrysvo ≥2 weeks before birth
- Infants who had sub-optimal protection
- Infants in 1st and 2nd season with risk conditions

Figure. Flowchart to guide which infants should receive nirsevimab in their 1st RSV season



When should you immunise each population?

Gestational age, seasonality and revaccination

Key information to consider:

- Seasonality epidemiology
- Immunisation product effectiveness/efficacy/immunogenicity particularly co-administration and duration of protection *(EtR domain: desirable effects)*
- Immunisation product safety *(EtR domain: undesirable effects)*
- Programmatic considerations *(EtR domains: equity and feasibility)*
- Managing decisions in the absence of data

Seasonality

RSV activity varies and is primarily climate-driven.

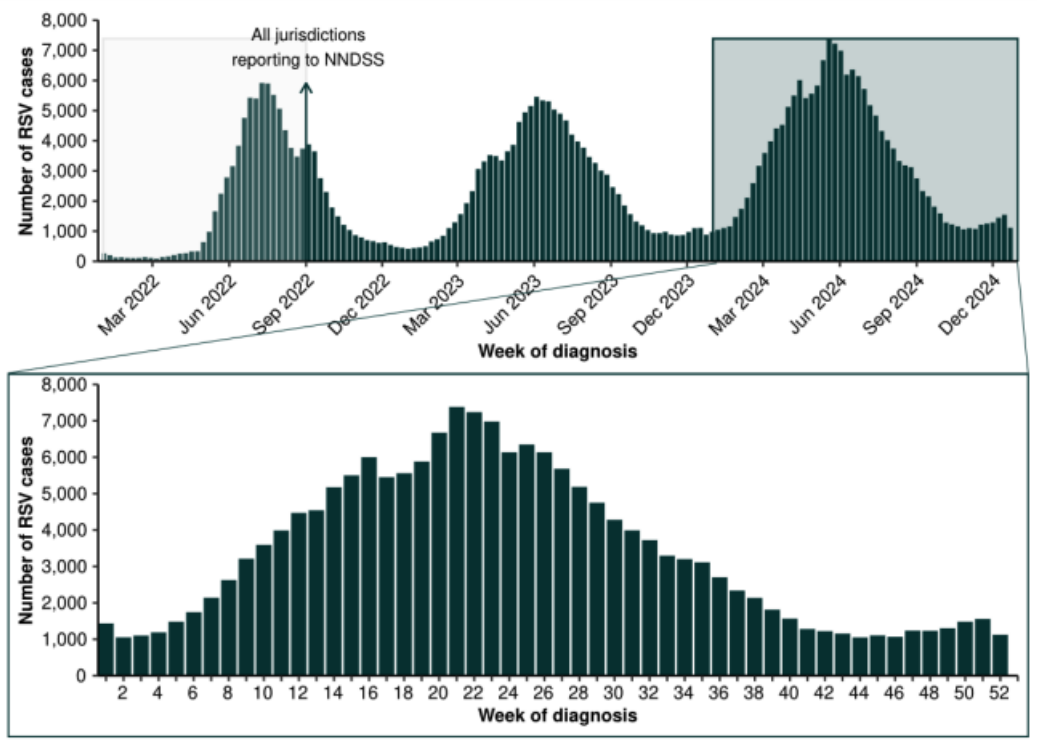
Seasonal outbreaks in most temperate regions in Australia occur during autumn and winter, usually between April and September.

The season peaks during June and July, often preceding the influenza season.

In tropical regions, RSV seasonality can be less pronounced and may coincide with rainy seasons.

2024 Annual Australian Respiratory Surveillance Report

Figure 9: Notified RSV cases by year and week of diagnosis*, Australia, January 2022 to December 2024



Source: National Notifiable Diseases Surveillance System (NNDSS), extracted 5 March 2025.
* RSV was added to the *National Health Security (National Notifiable Disease List) Instrument 2018* in July 2021. Following this some jurisdictions began notifying RSV cases to the NNDSS; however, RSV notification data was only received from all states and territories from 1 September 2022 and comprehensive national notification data became available after this point. For this reason, RSV notification trends in 2022 should be interpreted with caution as they are unlikely to be complete or representative.

Context

Trial of a similar maternal RSV vaccine was halted due to an imbalance of neonatal deaths due to preterm births

Gestational age and AESI of pre-term birth

Preterm birth and low birth weight outcomes in Abrysvo vaccine phase 3 trial data

	Abrysvo vaccine group N=3,568	Placebo group N=3,558
Preterm birth (<37 weeks)	5.7% (95% CI: 4.9%, 6.5%)	4.7% (95% CI: 4.1%, 5.5%)
Late preterm birth (≥34 to 37 weeks)	5.0% (CI not reported)	4.4% (CI not reported)
Infant deaths (all-cause) through 24 months of age	5 (0.1%)*	12 (0.3%)

*1 death was in an infant with extreme prematurity (27 weeks) and prematurity-related complications, and FDA was unable to exclude possibility of relationship to investigational product

Source: Fleming-Durata et al (2023) ACIP

Gestational age and AESI of pre-term birth

Time from vaccination to birth among preterm and term births: Abrysvo vaccine phase 3 trial data

Days from Vaccination to Birth	RSVpreF 120 µg (N=3568) n (%)	Placebo (N=3558) n (%)	Total (N=7126) n (%)
Preterm deliveries	201	169	370
≤7 days[a]	11 (5.5)	13 (7.7)	24 (6.5)
>7 days to ≤30 days[a]	69 (34.3)	58 (34.3)	127 (34.3)
>30 days[a]	121 (60.2)	98 (58.0)	219 (59.2)
At term deliveries	3364	3386	6750
≤7 days[a]	1 (<0.1)	2 (<0.1)	3 (<0.1)
>7 days to ≤30 days[a]	516 (15.3)	498 (14.7)	1014 (15.0)
>30 days[a]	2847 (84.6)	2886 (85.2)	5733 (84.9)

Source: Pfizer CSR 1008
Abbreviations: N=number of participants having birth date in the specified vaccine group. This value is the denominator for the percentage calculations; n = Number of participants in the specified category.
Note: Six participants have missing gestational age at birth in database, so are not included in counts above. Preterm/at term deliveries are determined based on gestational age at birth. Preterm=gestational age at birth less than 37 weeks. At term=gestational age at birth of 37 weeks or more. Number of days between vaccination and birth is calculated as birth date - vaccination date.
a. Percentages for this row are based on the number of preterm/at term deliveries, respectively.

Median gestational age at vaccination in trial was 31 weeks

Majority of preterm births occur >30 days from vaccination

Subgroup analysis of gestational age at birth among live births by country income level: Abrysvo vaccine phase 3 trial data

Country / Gestational Age at Birth	RSVpreF N=3568 n (%)	Placebo N=3558 n (%)
High income	2494	2484
≥24 weeks to <28 weeks	0	1 (<0.1)
≥28 weeks to <34 weeks	13 (0.5)	7 (0.3)
≥34 weeks to <37 weeks	113 (4.5)	118 (4.8)
≥37 weeks to <42 weeks	2360 (94.6)	2351 (94.6)
≥42 weeks	6 (0.2)	5 (0.2)
Upper middle income	964	961
≥24 weeks to <28 weeks	1 (0.1)	0
≥28 weeks to <34 weeks	7 (0.7)	4 (0.4)
≥34 weeks to <37 weeks	64 (6.6)	35 (3.5)
≥37 weeks to <42 weeks	882 (91.5)	906 (94.3)
≥42 weeks	9 (0.9)	15 (1.6)

In high-income countries, preterm birth rate was 5.1% in Abrysvo recipients vs 5.1% placebo recipients with most preterm births occurring between 34–37 weeks

Imbalance was most prominent in upper middle-income countries: 7.5% in Abrysvo recipients vs. 4.1% (39/961) in placebo recipients

Source: Fleming-Durata et al (2023) ACIP

Other ‘when’ questions

…but there is no data

Should these immunisation products be co-administered with other vaccines?

Should you revaccinate pregnant women in each pregnancy?

Should you immunise children with risk conditions entering their 2nd RSV season?

Should you immunise children with risk conditions with Beyfortus if their mother received Abrysvo?

What is the interval between vaccination and birth that would not confer sufficient maternal antibody transfer for protection?

What do you do in absence of data

Expert opinion

Should you immunise children with risk conditions entering their 2nd RSV season?

Epidemiology data suggests 2nd season risk remains high for some children with medical risk conditions.

The immunisation product is registered for this population.

Whilst there are no studies it is a reasonable assumption of benefit and similar safety profile to the 1st season dose.

First principles

What is the interval between vaccination and birth that would not confer sufficient maternal antibody transfer for protection?

It takes about two weeks after a mother receives the Tdap vaccine for pertussis antibody levels to peak.

Extrapolation of this may suggest recommending Beyfortus to infants if mother received Abrysvo less than 2 weeks before giving birth.

Await further data

Should you revaccinate pregnant women in each pregnancy?

Await further data but communicate and acknowledge lack of data and that decision will be made when it is available.

Discussion

Packet labelled B2.2

In groups of 2-3 – 10 minutes to review the data and answer the following questions:

1. Would you vaccinate pregnant women with Abrysvo seasonally or year-round?
   a) If seasonally, then what months of the year would you recommend?
2. Would you immunise infants and children with Beyfortus seasonally or year-round?
   a) If seasonally, then what months of the year would you recommend?
3. Would you keep the recommended gestational age for Abrysvo as the registered age of 24 to 36 weeks?
   a. If not, what gestational age would you recommend?
4. Do you agree with the conclusions for each scenario with no data?

Plenary discussion – 11 minutes group discussion including:

1. If there is consensus, do the Vaccine Presidents sign-off on the recommendations?
2. If there is no consensus, what is the proposal from the Vaccine Presidents?

What did ATAGI decide?

Seasonality

Both products were recommended for year-round vaccination programs.

Beyfortus recommendations note the seasonality of RSV and that it offers protection for at least 5 months, with early immunogenicity evidence suggesting some protection may remain for 6-12 months. Providers are recommended to consider timing of administration considering:

- Local seasonal patterns*
- administering shortly after birth for infants born just before or during the RSV season.
- For infants born after the RSV season, consider the likelihood of out-of-season RSV infection and risk of severe disease and consider delaying nirsevimab until just before the next RSV season, if appropriate
- shortly before the start of their 1st RSV season in older infants that remain at high risk.

*Whilst ATAGI recommended year-round vaccination – some states and territories based on their local seasonal patterns elected for seasons Beyfortus programs for their 2025 programs.

Gestational age

Abrysvo was recommended from 28 weeks' gestation.

- This was later than the lower registered age of 24 weeks
- This permitted vaccination beyond the registered age of 36 weeks

Is there a preference for a particular program or product?

1. **An infant Beyfortus-only program**
2. **Abrysvo maternal immunisation only program**
3. **A complementary/hybrid program.**

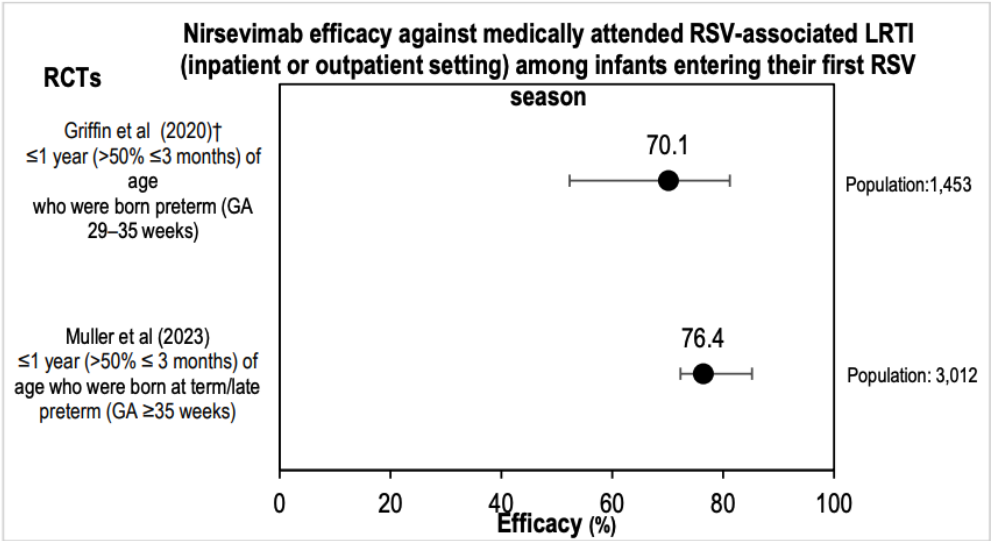
Key information to consider:

- Immunisation product effectiveness/efficacy/immunogenicity *(EtR domain: desirable effects)*
- Immunisation product safety *(EtR domain: undesirable effects)*
- Likely uptake and acceptability of an immunisation program *(EtR domains: values and acceptability)*
- Programmatic considerations *(EtR domains: equity and feasibility)*
- Legislative and funding considerations *(EtR domain: feasibility)*

Immunisation product efficacy

For access to full GRADE assessments for Beyfortus and Abrysvo scan QR code

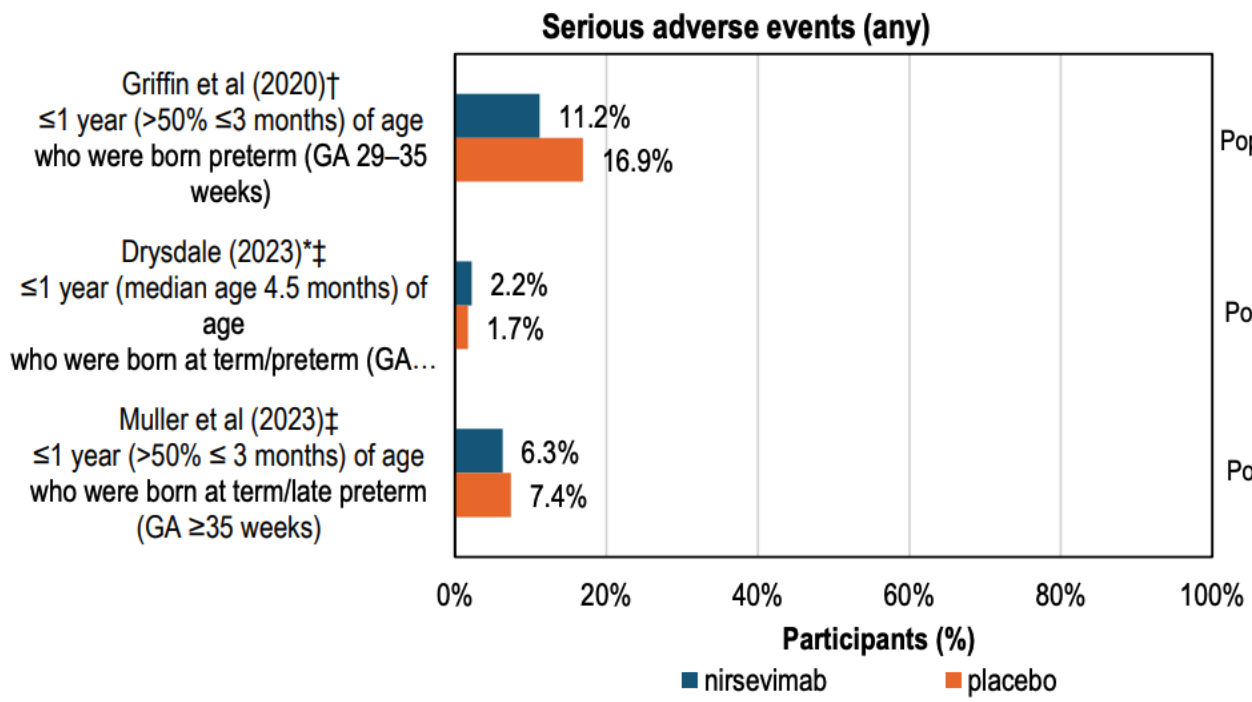
Sample of efficacy outcome from Beyfortus GRADE Summary of Findings (SoF) in infants in their first RSV season

Outcomes (studies)	Impact	№ of participants	Certainty of the evidence (GRADE)	Interpretation statement
CRITICAL OUTCOMES				
Vaccine efficacy against RSV (laboratory confirmed) medically-attended lower respiratory tract infection [LRTI]/lower respiratory tract disease [LRTD]) Assessed with: Detection of RSV on a central test (PCR assay), the presence of signs of lower respiratory tract involvement on chest auscultation, and the presence of ≥1 clinical signs indicating severe respiratory disease. Follow-up: 150 days (2 RCTs)	 † Nirsevimab dosing was not adjusted by weight. All participants received one 50 mg dose (not final product dosing).		⊕⊕⊕⊕ High	Sanofi nirsevimab results in a **large reduction** in medically attended RSV-associated LRTI among infants entering their first RSV season when compared with placebo.

Immunisation product safety

For access to full GRADE assessments for Beyfortus and Abrysvo scan QR code

Sample of safety outcome from Beyfortus GRADE Summary of Findings (SoF) in infants in their first RSV season

Outcomes (studies)	Impact	№ of participants	Certainty of the evidence (GRADE)	Interpretation statement
Serious adverse events (SAE)^ Follow-up: 360 days (3 RCTs)		Population: 1,447 Population: 8,035 Population: 2,994	⊕⊕⊕◯[c] Moderate	Sanofi nirsevimab likely results in **little to no difference** in any SAE when compared with placebo or standard care. Note, however, clinical trials are not powered to detect rare SAE.

Uptake and acceptability

Literature – Holland et al (2023), *Parental awareness and attitudes towards prevention of respiratory syncytial virus in infants and young children in Australia*

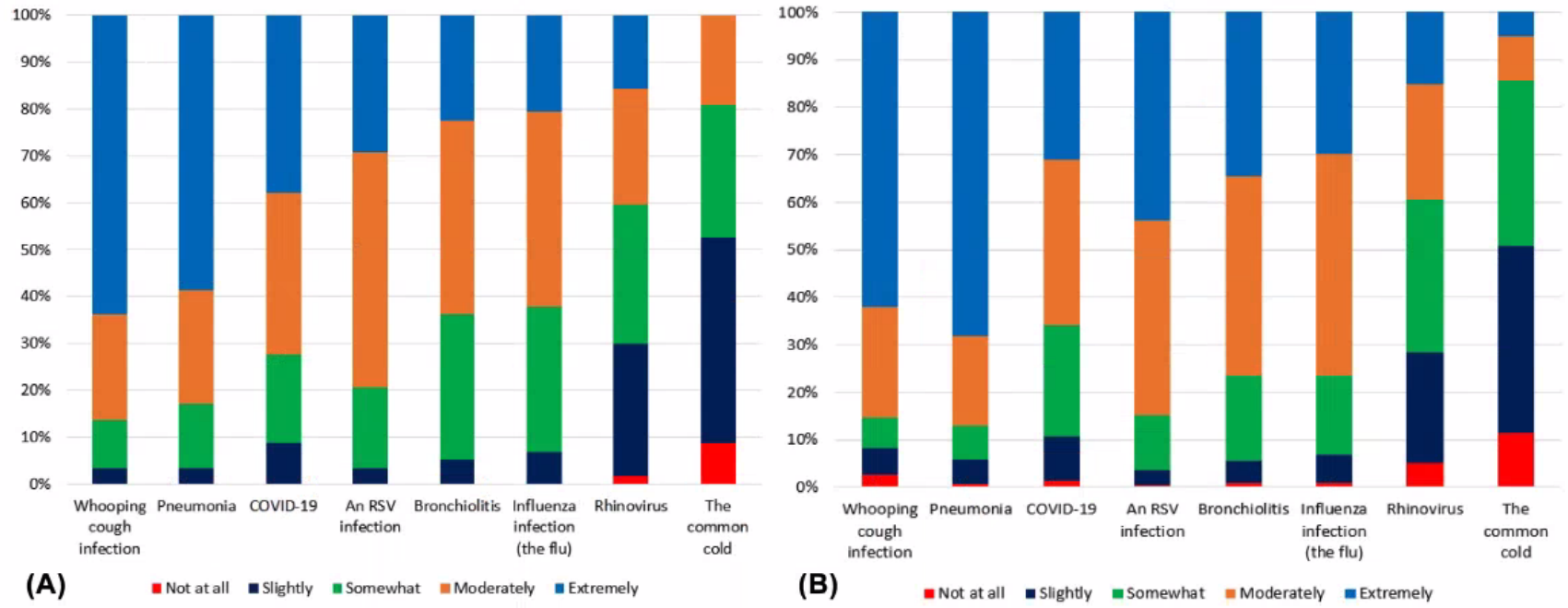


FIGURE 1 Level of worry towards childhood respiratory illnesses in the future parent subgroup (A) and current parent subgroup (B). Excludes participants who did not respond. Participants were asked about how worried they would be if their young children were to contract such conditions. Conditions are listed in order of level of worry (from left to right).

Legislative and funding considerations

Whilst ATAGI does not determine vaccine funding, considerations are sometimes made if funding impacts on the feasibility or likely up-take of an immunisation product, especially in the context of multiple possible programs or products.

Some considerations for the RSV program preference

- Neither product is NIP-funded.
- If Beyfortus was recommended by PBAC, legislative change would need to occur before it could be included on the NIP as it was a monoclonal antibody rather than a vaccine.
- Varying levels of state and territory funding for Beyfortus and uncertainty around longevity of such programs.

Plenary discussion (5 mins) - Programmatic considerations

What are some pros and cons of each programmatic approach?

Infant Beyfortus-only program

Abrysvo maternal immunisation only program

Complementary/hybrid program

Discussion

Packet labelled B2.3

At your tables – 7 minutes to review the data and answer the following question:

1. Rank the three possible infant protection programs in order of preference
   a) A Beyfortus-only program
   b) Maternal immunisation only program
   c) A complementary/hybrid program.
2. Briefly outline the rationale for why you have preferenced the program options in this way

Plenary discussion – 6 minutes:

1. If there is consensus, do the Vaccine Presidents sign-off on the recommendations?
2. If there is no consensus, what is the proposal from the Vaccine Presidents?

Programmatic considerations

Infant Beyfortus-only program

- ✓ A single immunisation product program is easier to implement
- ✓ A program that would be accessible to all infants including those at high-risk
- ❖ An additional injection at birth
- ❖ No studies on safety and efficacy of second season use for children with risk conditions
- ❖ Potential for supply issues

Abrysvo maternal immunisation only program

- ✓ A single immunisation product program is easier to implement
- ❖ Crowded maternal vaccine space
- ❖ Some infants, including some at the highest risk of severe disease, who will remain unprotected due to their mother not receiving an antenatal dose or being ineligible to receive one due to gestational age (i.e., infants born before 28 weeks gestation).
- ❖ Potential for supply issues

Complementary/hybrid program

- ✓ Could maximise potential coverage.
- ✓ Mitigate against any supply issues
- ✓ Could mitigate potential barriers to access of either product
- ❖ Administrative load on provides as requires maternal vaccination status to be determined for Beyfortus eligibility
- ❖ Absence of efficacy and safety data on Beyfortus following maternal vaccination with Abrysvo in risk groups

What did ATAGI decide?

Complementary program

ATAGI recommended a complementary program of both RSV immunisation products

Summary and closing remarks

NCIRS National Centre for Immunisation Research and Surveillance Australia