IMMUNISATION COALITION

2024 WEBINAR

RESPIRATORY SYNCYTIAL VIRUS UPDATE

WEDNESDAY 26 June | 6pm–7pm AEST

Presenter: Dr Gemma Saravanos, PhD RN
Moderator: Dr Andrew Minton, PhD

Moderator

Dr Andrew Minton, PhD

The management of the Immunisation Coalition is undertaken by our Chief Executive Officer, Andrew Minton.

Andrew has over 25 years of commercial and medical experience across a number of disease areas. Originally from New Zealand, he has worked in the United Kingdom, Sweden and Germany before settling in Australia in 2005.

His more recent roles have included business development, marketing, medical affairs, and the development of Healthcare Professional-specific CPD programs.

He now looks forward to continuing to develop the Immunisation Coalition as a leader and voice of vaccine-related information and services to healthcare providers, with the goal of improving population health against harmful infectious diseases.

Housekeeping

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- Please type any questions for the speakers in the Q&A box (not Chat) throughout the meeting
- There will be a very short survey (Evaluation Form) coming after the event closes. We look forward to hearing your feedback.
- A recording of this event and the speaker slides will be made available on the Immunisation Coalition’s website soon

Presenter

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Dr Gemma Saravanos

PhD RN BN GradCert (ClinNurs) BioMedSci(Hons)

Associate Lecturer - Academic Fellow: The University of Sydney | Faculty of Medicine & Health | Susan Wakil School of Nursing & Midwifery

Post-Doctoral Research Fellow: The Children's Hospital Westmead Clinical School, Centre for Paediatric & Perinatal Infection Research

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Please indicate the profession or expertise area that most closely represents your background:

1. GP / Medical Practitioner
2. Nurse / Midwife / Immunisation Practitioner
3. Researcher / Educator
4. Pharmacist
5. Other healthcare worker
6. Other

Respiratory Syncytial Virus (RSV) Update

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Learning Outcomes:

Following this webinar, participants will be able to:

- Describe the burden and impact of RSV disease
- Describe and understand the role of national notifiable RSV disease surveillance
- Identify passive and active RSV immunisation approaches and target groups
- Describe the current RSV immunisation landscape with a focus on the Australian setting
- Consider your current and potential future role in RSV prevention

Respiratory Syncytial Virus (RSV) Prevention: Where are we now?

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Immunisation Coalition Art Prize Winner 2021 “The Cure” by Brooke Daljac 14, Western Australia. https://www.immunisationcoalition.org.au/2021-art-prize/

- Burden of RSV Disease
- National RSV Surveillance in Australia
- The RSV Immunisation Landscape
- RSV Immunisation in Australia:
  - Infants & Children
  - Older Adults
- RSV Education & Advocacy
- Final Thoughts on RSV Prevention

Burden of RSV Disease

Burden of RSV Disease: A tiny virus with a big impact!

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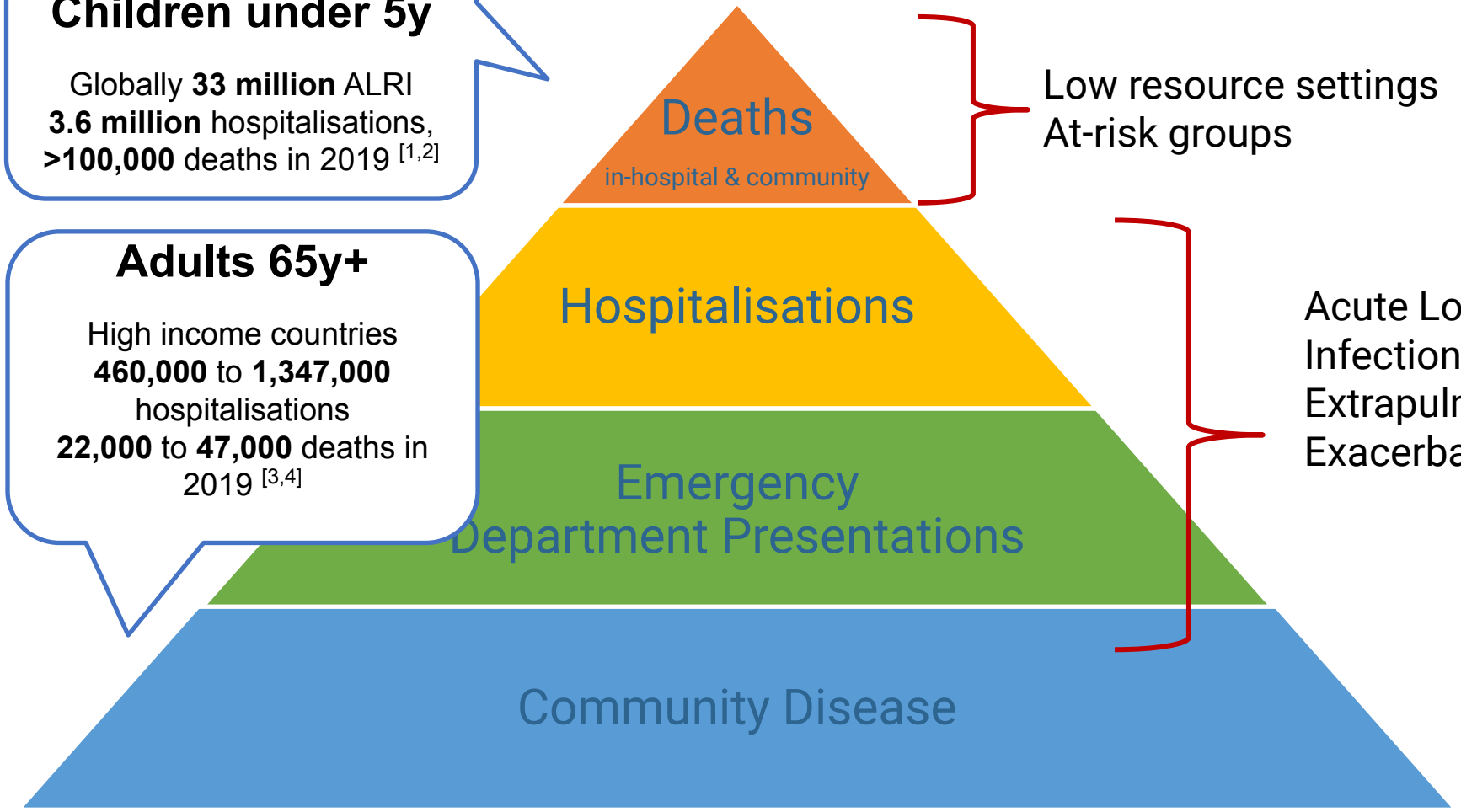
Children under 5y

Globally **33 million** ALRI
3.6 million hospitalisations,
>100,000 deaths in 2019 [1,2]

Adults 65y+

High income countries
460,000 to **1,347,000** hospitalisations
22,000 to **47,000** deaths in 2019 [3,4]



Low resource settings
At-risk groups

Acute Lower Respiratory Infection (ALRI)
Extrapulmonary presentations
Exacerbation of chronic disease

Upper Respiratory Tract Infection
Otitis media

[1] Wang et al 2024 https://doi.org/10.1016/S0140-6736(24)00138-7; [2] Burrell et al. 2023 https://doi.org/10.1016/j.prrv.2023.07.004; [3] Li et al. 2023 https://doi.org/10.1007/s40121-023-00792-3
[4] Fleming et al. 2015 https://doi.org/10.1186/s12879-015-1218-z

Burden of RSV Disease: A tiny virus with a big impact!

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- Childhood Asthma - infant RSV infection may cause ~15% later onset asthma [1]
- Sustained functional decline in adults – general and cardiopulmonary decline [2]
- Quality of Life e.g. RSV symptoms, anxiety and stress, disrupted activities [3]
- Healthcare resource consumption, pressure and cost
  - ‘Winter Surge’ [4]
  - Overuse of low-value interventions [5]
  - Overuse of antibiotics [6]
  - –>AU$6,350 per hospitalisation and AU$20,000 per intensive care unit admission [7, 8]
- Healthcare associated RSV infection [9]

[1] Rosas-Salazar et al. 2023 https://doi.org/10.1016/S0140-6736(23)00811-5; [2] Ubamadu et al. 2024 https://doi.org/10.1007/s40121-024-00974-7; [3] Díez-Gandía et al. 2021 https://doi.org/10.1186/s12879-021-06629-z; [4] Elliot et al. 2008 https://doi.org/10.1093/pubmed/fdn003; [5] Schroeder et al. 2023 doi:10.1001/jamanetworkopen.2021.0157; [6] van Houten et al. 2018 DOI: 10.1097/INF.0000000000001981; [7] Homaira et al. 2016 doi: 10.1017/S0950268815003015; [8] Pham et al. 2019 https://doi.org/10.1111/jpc.14491 [9] Lee et al. 2016 https://doi.org/10.1016/j.jmii.2014.08.020

Burden of RSV Disease: A tiny virus with a big impact!

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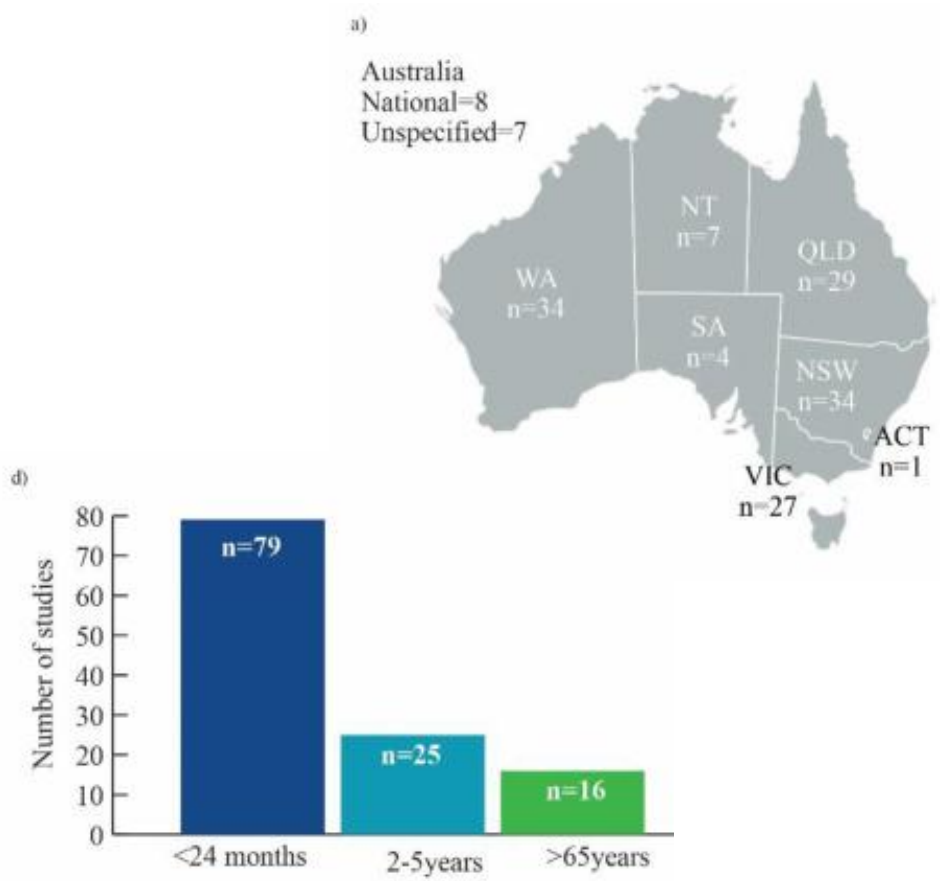
Scoping review of RSV across the lifespan in Australia and New Zealand [1]

- Most studies focused on children and were conducted in a hospital setting
- Adult studies were less common (27%, 41)
- Few studies in primary care (6, 4%)
- Few studies reported economic burden (6, 4%)
- No study quantified indirect or social costs



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National RSV Surveillance in Australia

National RSV Surveillance in Australia

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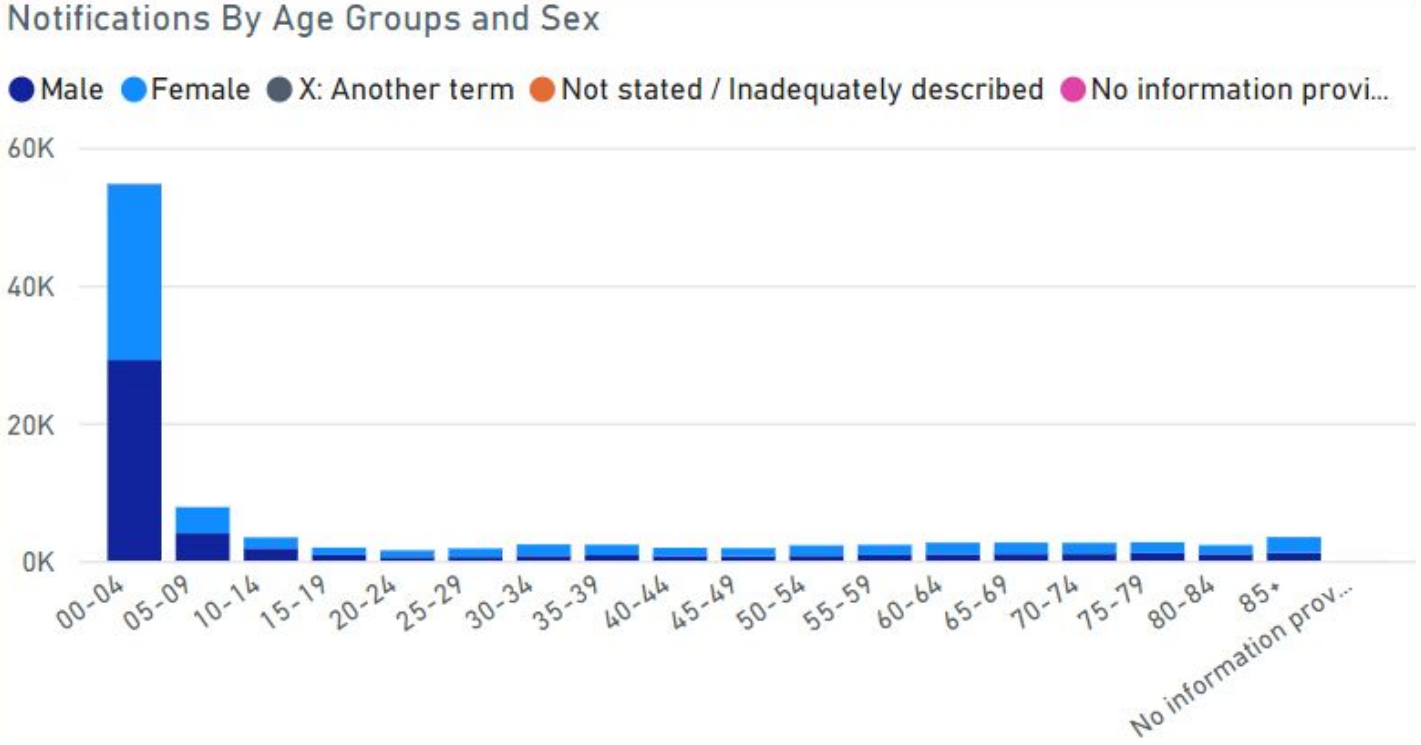
National Notifiable Disease Surveillance System (NNDSS)

- Nationally notifiable since ~2022 (laboratory confirmed)
- For 2024 **100,368** notifications in 2024 at 19th June

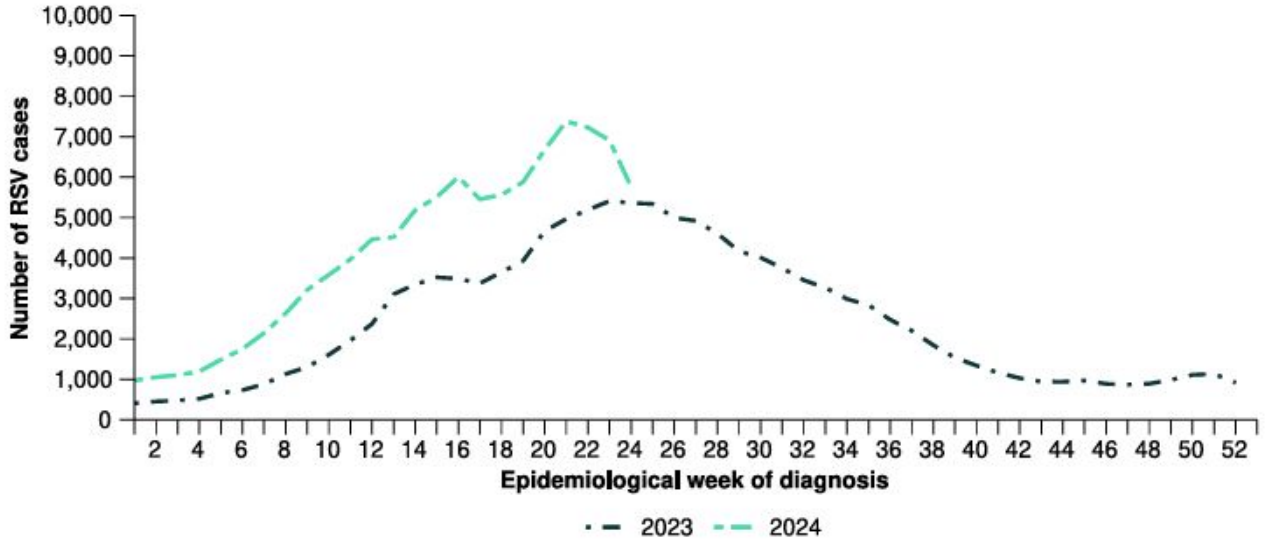


State	2024 Count	%
NSW	48,474	48.3
QLD	23,625	23.5
VIC	19,397	19.3
SA	3,324	3.3
ACT	1,823	1.8
WA	1,789	1.8
NT	1,124	1.1
TAS	812	0.8
TOTAL	**100,368**	

RSV notifications by age groups and sex in 2024 as at 19th June 2024 source: https://nindss.health.gov.au/pbi-dashboard/

National RSV Surveillance in Australia

Figure 10: RSV cases notified to the NNDSS by year and week of diagnosis*, Australia, 2023 to 16 June 2024



* RSV became notifiable in all states and territories on 1 September 2022. Comprehensive national data for RSV are only available from 2023 onwards.

https://www.health.gov.au/resources/collections/australian-respiratory-surveillance-reports-2024

National RSV Surveillance in Australia

Table 1: Notifications to the NNDSS and notification rate per 100,000 population by disease, five-year age group, and jurisdiction*†, Australia, 1 January to 2 June 2024

	COVID-19			Influenza			RSV		
	Reporting fortnight (n)	Year to date (n)	Year to date (rate)	Reporting fortnight (n)	Year to date (n)	Year to date (rate)	Reporting fortnight (n)	Year to date (n)	Year to date (rate)
Age group (years)									
0–4	1,429	10,499	692.5	2,225	8,895	586.7	6,764	48,424	3,194.2
5–9	567	2,574	159.8	3,102	9,937	617.1	1,397	6,289	390.5
10–14	681	2,693	162.5	2,140	6,236	376.3	691	2,515	151.7
15–19	626	3,531	219.5	1,108	4,326	268.9	340	1,562	97.1
20–24	615	4,360	251.7	688	3,553	205.1	210	1,289	74.4
25–29	758	5,651	294.1	724	3,803	197.9	263	1,521	79.2
30–34	916	6,460	325.8	883	4,288	216.3	367	2,036	102.7
35–39	1,028	6,878	354.9	1,055	4,839	249.7	327	2,004	103.4
40–44	1,025	6,616	371.6	1,029	4,533	254.6	307	1,588	89.2
45–49	947	6,073	376.2	829	3,758	232.8	289	1,497	92.7
50–54	975	6,602	392.9	667	3,691	219.7	326	1,895	112.8
55–59	969	6,572	431.3	584	3,196	209.8	361	1,947	127.8
60–64	988	6,890	454.3	508	3,062	201.9	357	2,243	147.9
65–69	1,088	7,305	550.5	401	2,585	194.8	417	2,267	170.8
70+	7,141	45,265	1,401.4	1,122	7,873	243.7	1,655	9,339	289.1

https://www.health.gov.au/resources/collections/australian-respiratory-surveillance-reports-2024

National RSV Surveillance in Australia

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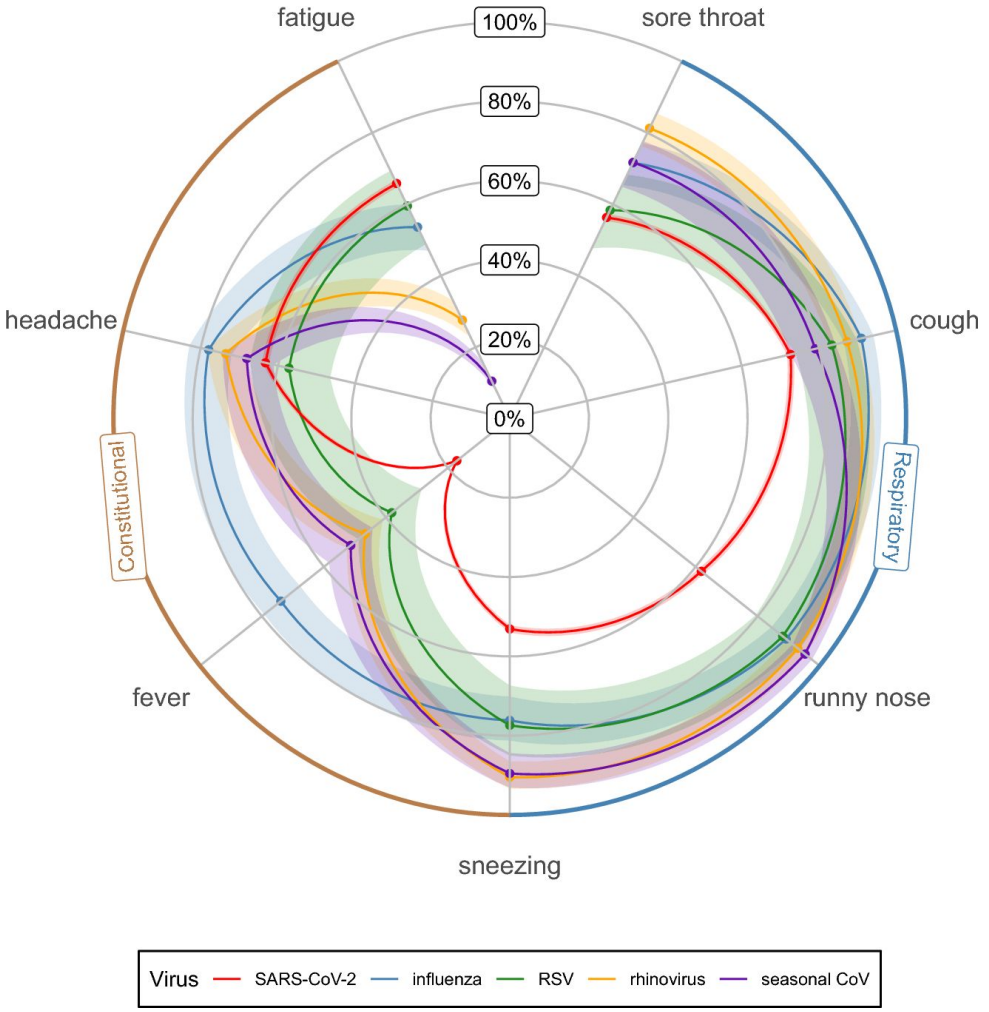
The case for respiratory pathogen testing:

- Overlapping symptomatology of respiratory infections [1]
- Testing can support [2,3]
  - Accurate surveillance & disease burden estimates
  - Vaccine effectiveness studies
  - Clinical management e.g. antivirals for influenza or COVID
  - Other benefits e.g. reduce antibiotic use? public awareness?
- Need for evidence-based clinical guidelines [3]

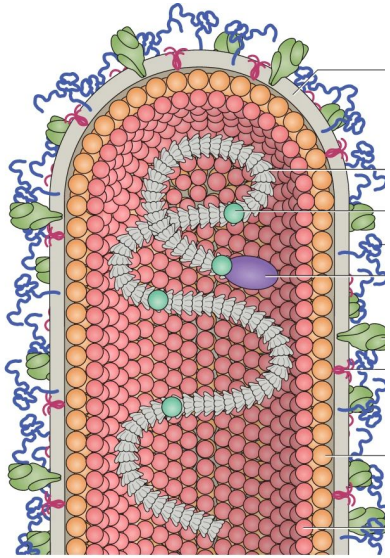


[1] Geismar et al.2023 https://doi.org/10.1038/s41598-023-38869-1 ; [2] Clark et al. 2023 https://doi.org/10.1016/j.jinf.2023.03.005 ; [3] Burrell et al. 2023 https://doi.org/10.1016/j.prrv.2023.07.004

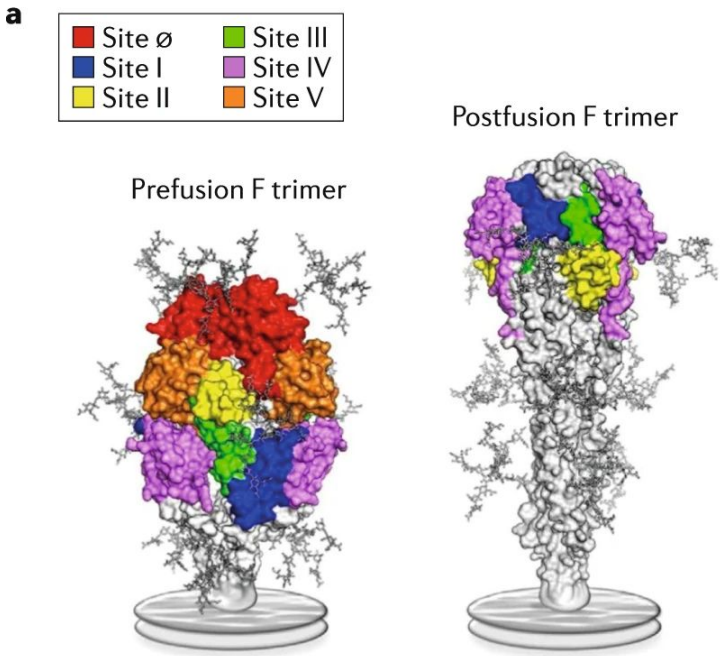
The RSV Immunisation Landscape

RSV Immunisation Approaches by Group and Product Type

Paediatric	Maternal	Older Adults
Passive immunisation (monoclonal Ab) Active vaccination • Live attenuated • Nucleic acid • Recombinant vectors	Active vaccination of mothers to protect infants via passive transfer of antibodies • Protein-based (F) • Nucleic acid	Active vaccination • Protein-based (F) • Nucleic acid • Recombinant vectors



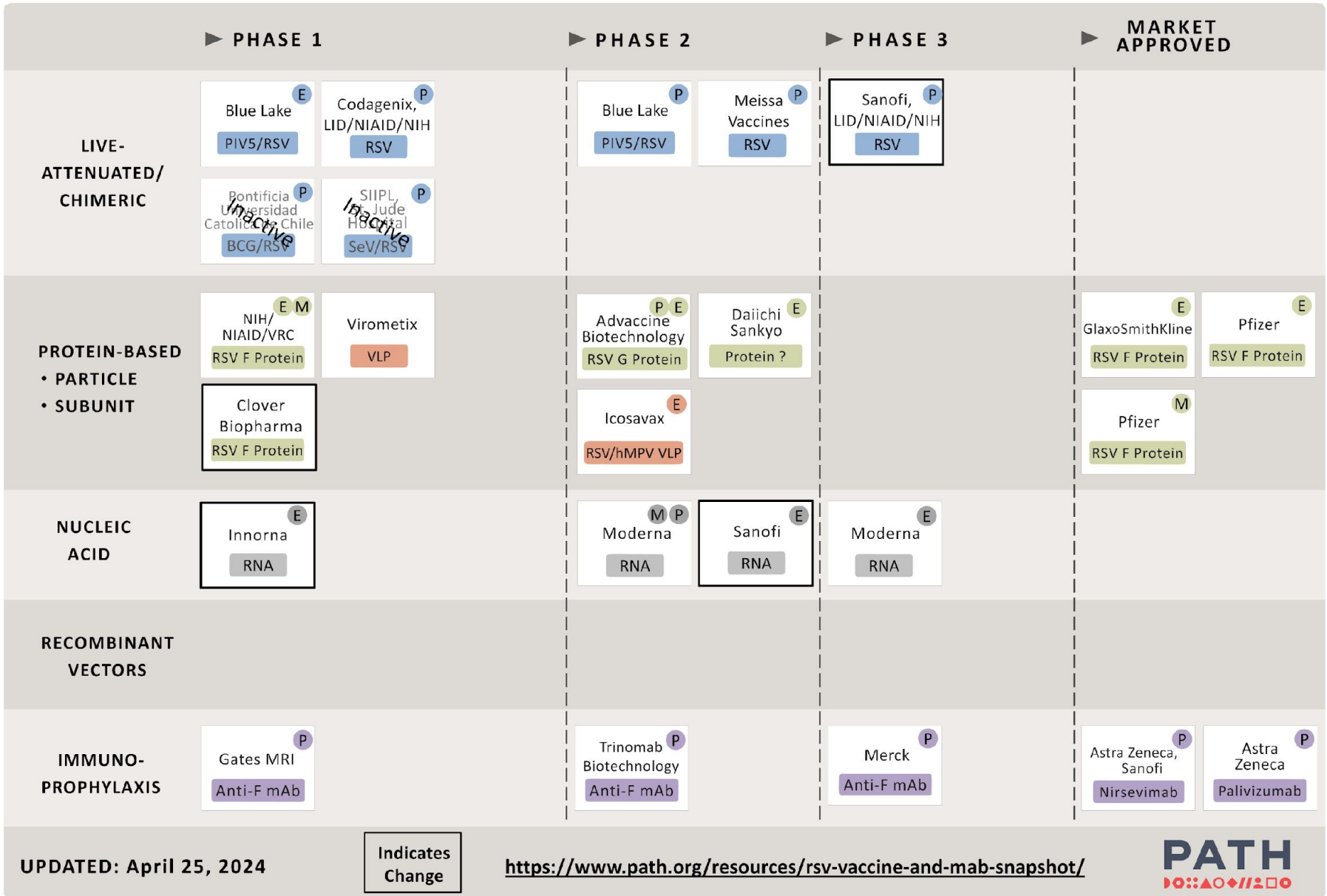
- **F (Fusion) protein**
  - Highly conserved
  - Most common vaccine & mAb target
    - pre-fusion conformation
- **G (attachment) glycoprotein**
  - Variable



https://doi.org/10.1038/s41579-019-0149-x

RSV Vaccine and mAb Snapshot

TARGET INDICATION: P=PEDIATRIC M=MATERNAL E=ELDERLY



UPDATED: April 25, 2024

Indicates Change

https://www.path.org/resources/rsv-vaccine-and-mab-snapshot/

PATH

Real world implementation in Galicia, Spain

- Publicly funded immunisation (mAb nirsevimab) campaign: Sep 2023 to Mar 2024 [1]
  - Seasonal: for all newborns (birth hospital)
  - Catch-up: for 0-6mo (primary care)
  - High risk children up to 24mo (reference hospital)
- High coverage: 9,408 (91.7%) eligible infants received nirsevimab [2]
  - Effectiveness against RSV LRTI hospitalisation 82·0% (95% CI 65·6–90·2)
  - Number needed to treat was 25 (IQR 24-32)

[1] Martinon-Torres et al. 2023 https://doi.org/10.2807/1560-7917.ES.2023.28.49.2300606; [2] Ares-Gomez et al. 2024 https://doi.org/10.1016/S1473-3099(24)00215-9; Image: immunisation campaign in Galicia, Spain from Journal of Infectious Diseases 2024 (229) Supplement 1

Real world implementation in Catalonia, Spain

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- Similar program (mAb nirsevimab) demonstrated reductions in RSV related hospitalisations and primary care visits [1]
- High coverage: 76.3% within the first month of the immunisation campaign
- Retrospective cohort study including 23,127 infants (87.2%) immunised against RSV:
  - Primary care attended bronchiolitis ↓48.1% (42.4% to 53.3%)
  - Emergency visits for bronchiolitis ↓ 55.4% % (48.4% to 61.5%)
  - RSV hospitalisations ↓ 87.6% 87.6% (82.1% to 91.4%)
  - RSV ICU admissions ↓ 90.1% (76.3% to 95.9%)

[1] Coma E, et al. Arch Dis Child 2024;0:1–6. doi:10.1136/archdischild-2024-327153

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RSV Immunisation in Australia – where are we now?

RSV Immunisation in Australia – Infants & Children

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Product	Target Group	TGA Approval	NIP or funded program	Private Market	Clinical Guidance
Synagis (palivizumab) Sobi, 5 dose monoclonal antibody	Infants up to 24mo of age at extremely high risk of severe RSV disease	1999	No Funding varies by state/territory	No	Refer to local guidelines
Beyfortus (nirsevimab) Sanofi-Aventis, single-dose monoclonal antibody	Newborns/infants up to 24mo of age	Nov 2023	No State-funded programs (NSW, Qld, WA)	No	See ATAGI Statement
Abrysvo “Ah-breeze-vo” Pfizer, protein subunit vaccine	Maternal vaccination to protect infants from birth up to 6 months of age	Mar 2024	No	TBD	TBD

Therapeutic Goods Administration (TGA); National Immunisation Programme (NIP); Australian Technical Advisory Group on Immunisation (ATAGI)); to be determined (TBD)

www.ncirs.org.au/media/1139 | https://ncirs.org.au/media/1140 | www.health.gov.au/sites/default/files/2024-03/atagi-statement-on-nirsevimab-2024.pdf

RSV Immunisation in Australia – Beyfortus (nirsevimab)
Babies and infants to 24 months

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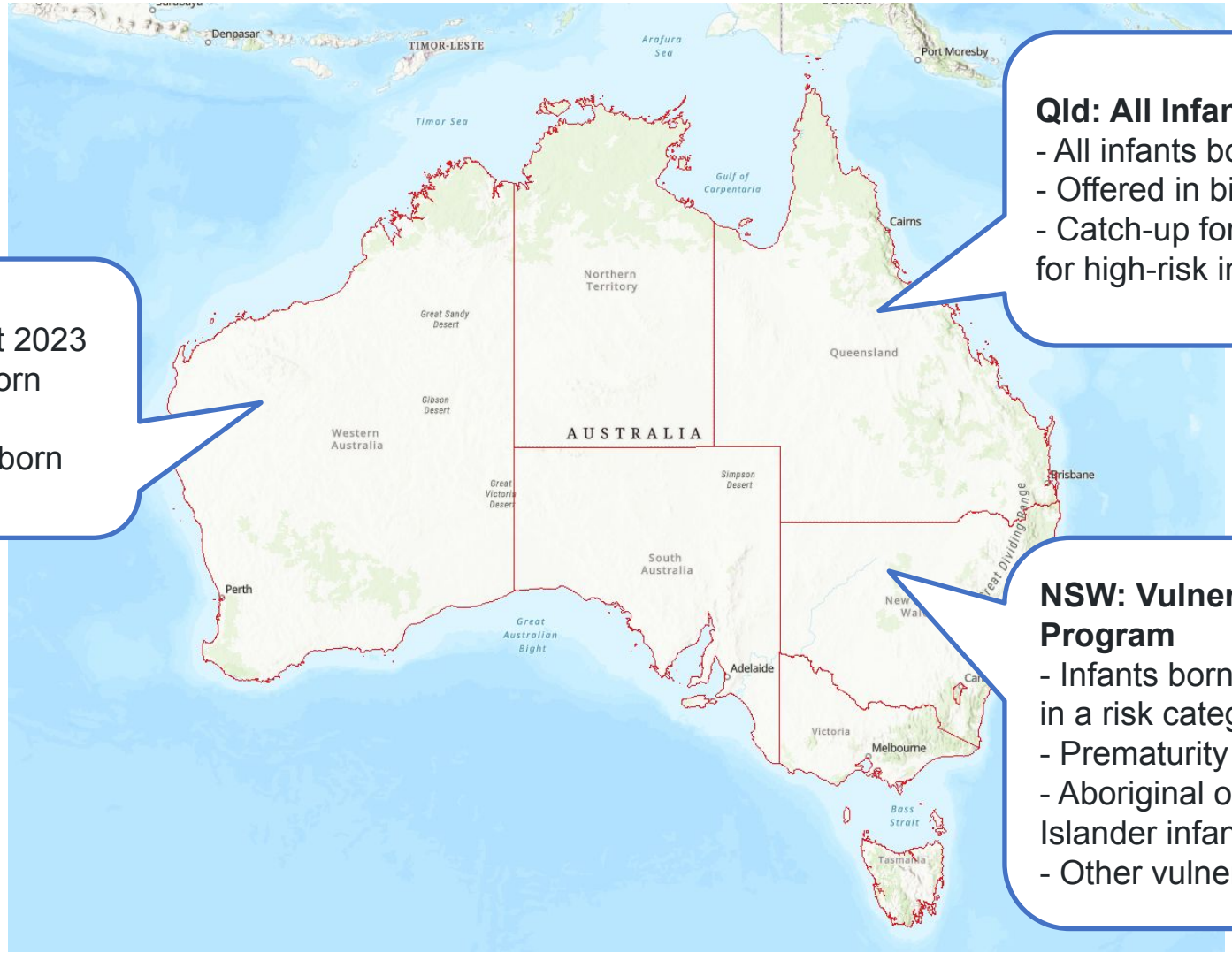
WA: All Infants
- All infants born from Oct 2023
- All Aboriginal children born from Oct 2022
- Some high- risk infants born from Oct 2022)



Qld: All Infants
- All infants born from Feb 2024
- Offered in birth hospitals
- Catch-up for up to 8mo or 20mo for high-risk infants (primary care)

NSW: Vulnerable Babies Program
- Infants born from Nov 2023 AND in a risk category
- Prematurity <37w
- Aboriginal or Torres Strait Islander infants
- Other vulnerable infants

https://maps.abs.gov.au/index.html | www.health.nsw.gov.au/immunisation/pages/nirsevimab-professionals.aspx | www.health.wa.gov.au/Articles/N_R/Respiratory-syncytial-virus-RSV-immunisation | www.health.qld.gov.au/data/assets/pdf_file/0017/1322144/rsv-prevention-program-clinical-guide.pdf

RSV Immunisation in Australia – Beyfortus (nirsevimab)
Babies and infants to 24 months

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"Jayedene, from Junjuwa community, said she was extremely proud that Sandie was the first baby in the Kimberley immunised under the program and wanted to spread the word to new parents in the region."

19th April 2024

https://www.wacountry.health.wa.gov.au/News/2024/04/19/First-Kimberley-baby-receives-life-saving-RSV-immunisation

RSV Immunisation in Australia – Beyfortus (nirsevimab)
Babies and infants to 24 months

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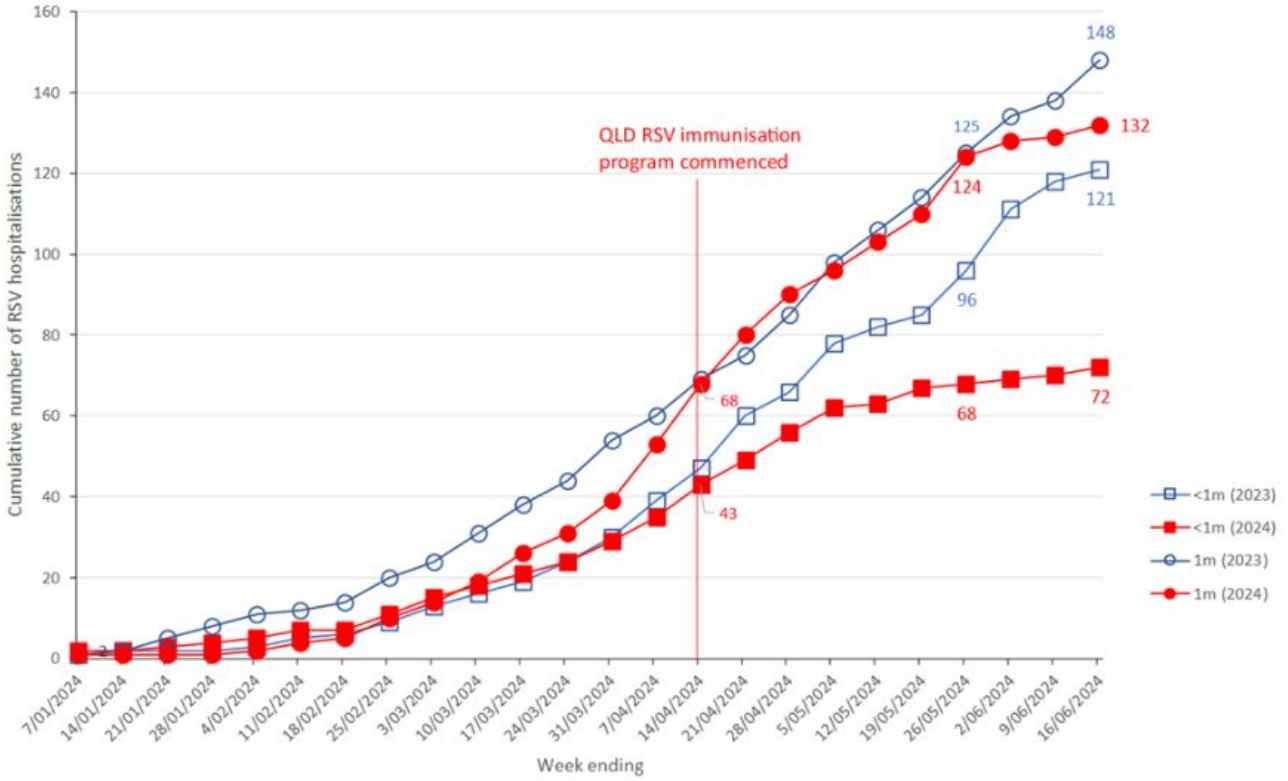
"Government's free RSV immunisation program shows no immunised newborns hospitalised for RSV since its launch"

Queensland Government, 20th June 2024



https://statements.qld.gov.au/statements/100626

RSV Immunisation in Australia – Beyfortus (nirsevimab)
Babies and infants to 24 months

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Availability is currently limited to specific state-based programs (supply limitations)

Populations likely to gain most benefit should be prioritised (Table 1)

Other considerations:

- Risk of severe disease is increased for infants with multiple risk factors, and for Aboriginal and Torres Strait Islander infants
- Infants with reduced access to acute care due to remoteness
- Palivizumab as an alternate RSV mAb where eligible and available.

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.

www.health.gov.au/sites/default/files/2024-03/atagi-statement-on-nirsevimab-2024.pdf

RSV Immunisation in Australia – Beyfortus (nirsevimab)
Babies and infants to 24 months

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Administration & Dose

- Single intramuscular injection

First season

- 50 mg in 0.5 mL if weight is <5 kg (purple)

- 100 mg in 1 mL if weight is ≥5 kg (light blue)

Second season (if indicated)

- 200 mg administered as 2 × 100 mg (2 mL total)

Timing

- Administer as soon as possible AND to maximise protection during peak RSV periods (~Mar to Sep)

- Provides protection for at least 5 months

Safety & Co-administration

- Co-administer with routine vaccines

- Unlikely to interfere with active immunisation response

Contraindications

- Allergy to product ingredients

- Confirmed recent RSV infection

Storage

- Cold chain 2-8°C refrigerator storage, room temperature for up to 8 hours (then discard)

www.health.gov.au/sites/default/files/2024-03/atagi-statement-on-nirsevimab-2024.pdf | https://www.medsinfo.com.au/api/documents/Beyfortus_PI?format=pdf | https://www.health.nsw.gov.au/immunisation/pages/nirsevimab-professionals.aspx

RSV Immunisation in Australia - Older Adults

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Product	Target Group	TGA Approval	NIP or funded program	Private Market	Clinical Guidance
Abrysvo "Ah-breeze-vo" Pfizer, protein subunit vaccine	Adults aged ≥60 years	Mar 2024	TBD	TBD	TBD
Arexvy "Ah-rex-vee" GSK, protein subunit vaccine with adjuvant	Adults aged ≥60 years	Jan 2024	TBD	Available (*$280)	See ATAGI statement
Moderna RSV mRNA-1345 vaccine	Adults aged ≥60 years	Submitted Under Evaluation (Priority review)	TBD	TBD	TBD

Therapeutic Goods Administration (TGA); National Immunisation Programme (NIP); Australian Technical Advisory Group on Immunisation (ATAGI); to be determined (TBD)
www.ncirs.org.au/media/1139 | https://www.health.gov.au/resources/publications/atagi-statement-on-the-clinical-use-of-arexvy-rsv-pre-f3-vaccine-for-rsv?language=en |
*https://hmri.org.au/news-article/everything-you-need-know-about-new-rsv-vaccines | https://www.tga.gov.au/resources/prescription-medicines-under-evaluation/tbc-moderna-australia-pty-ltd

RSV Immunisation in Australia - Arexvy

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ATAGI Recommendation

- Adults aged ≥75 years

- Aboriginal and/or Torres Strait Islander peoples aged 60 to 74 years

- Adults aged 60 to 74 years with medical conditions

- Adults aged 60 to 74 years can consider

**private market only*

Administration & Dose

- Adjuvanted recombinant RSV vaccine

- 0.5mL single intramuscular injection

Timing

- Any time of the year

Safety & Co-administration

- Co-administer with routine vaccines (potential risk of increased mild-moderate adverse events)

Contraindications

- Allergy to product ingredients

Storage

- Powder and suspension for reconstitution

- Cold chain 2-8°C

- After reconstitution administer immediately or within 4 hours (room temperature then discard)

www.health.gov.au/sites/default/files/2024-02/atagi-statement-on-the-clinical-use-of-arexvy-rsv-pre-f3-vaccine-for-rsv_0.pdf | https://au.gsk.com/media/6889/arexvy_pi_au.pdf |

RSV Immunisation in Australia - Abrysvo

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TGA approved for the following therapeutic use in <u>two population groups</u> (ATAGI advice will soon be available)

- Active immunisation of ***pregnant women*** between 24-36 weeks of gestation for prevention of lower respiratory tract disease caused by RSV in infants from birth through 6 months of age (Pregnancy category A)

- Active immunisation of ***individuals 60 years of age and above*** for prevention of lower respiratory tract disease caused by respiratory syncytial virus RSV.

Administration & Dose

- Recombinant RSV vaccine (no adjuvant)

- 0.5mL single intramuscular injection

Storage

- Powder and suspension for reconstitution

- Cold chain 2-8°C refrigerator storage

- After reconstitution administer immediately or within 4 hours (room temperature then discard)

https://www.tga.gov.au/resources/auspmd/abrysvo;
https://www.tga.gov.au/how-we-regulate/monitoring-safety-and-shortages/report-adverse-event-or-incident/report-adverse-events-medicines-and-biologicals/black-triangle-scheme |
www.tga.gov.au/sites/default/files/2024-05/auspar-abrysvo-240502-pi.pdf

Which is the best RSV immunisation product and strategy?

https://www.cdc.gov/coronavirus/2019-ncov/images/vaccines/covid-vaccine-widget-bandaid.jpg

Any TGA approved product is considered to be safe and effective for the group in which it is indicated

Generally - the best product, is the one that is administered.

Will depend on:

- What is available?
- What are the costs involved?
- What are the needs and preferences of the patient?

Summary of immunisation products and strategies

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Seasonal or year-round strategy?

Monoclonal antibodies or maternal vaccination?

Vaccine efficacy (VE) against severe RSV-related lower respiratory tract infection

- Beyfortus (nirsevimab, Sanofi-Aventis) through 150 days **78.6%** (95% CI 48.8, 91.0)
- Abrysvo (Pfizer maternal vaccine at 24-36w) from birth to 180 days **69.4%** (97.58%: 44.3, 84.1)

Adjuvanted? Protein-based? mRNA?

VE against lower respiratory tract disease (LRTD) (*1st season)

- Arexvy (adjuvant, GSK) **94.1%** (95% CI 62.4, 99.9) [Severe LRTD in healthy adults ≥60y]
- Abrysvo (Pfizer) **84.6%** (95% CI 32.0, 98.3) [Medically attended LRTD in healthy adults ≥60y]
- mRNA (Moderna) **63.0%** (95% CI: 37.3–78.2) [LRTD with ≥3 symptoms in healthy adults ≥60y]

Education and Advocacy

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Australian RSV Community Awareness Study (n=1,992) [1]

- Current parents, pregnant or planning children
- High awareness (70-90%) of RSV
  - Higher odds ratio for current parents, Australian born, university educated
  - Less awareness of RSV association with severe disease e.g. pneumonia (50-64%)
- High level of acceptance for maternal vaccines (79%) and infant immunisation (82%)
- Information sources on infectious disease and immunisation
  - Google (including government websites)

Education and Advocacy

Talking with your patients about RSV and immunisation [1-5]

- Assess knowledge base
- Tailor your message
- Be opportunistic and remove barriers
- Recommend and provide/or refer
- Acknowledge uncertainty (availability, benefit-risk)
- Consider vaccine equity
- Build trust and leave the door open

https://www.ifa.org.au/uniteagainstrsv

[1] Holland et al. (2024) https://doi.org/10.1111/apa.17127; [2] https://www.immunisationcoalition.org.au/; [3] https://www.ifa.org.au/; [K] Koirala et al. 2024 https://theconversation.com/from-rsv-to-meningococcal-b-we-must-ensure-equitable-access-to-childhood-immunisations-226392; [5] The BeSD Framework https://www.who.int/publications/i/item/9789240049680

Final Thoughts on RSV Prevention in Our Communities

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- Share information about RSV and immunisation with your patients
- Recommend and provide RSV immunisation as possible (ATAGI and AIR)
- Report adverse events following immunisation
- Consider respiratory pathogen testing
- Promote basic infection prevention and control for all respiratory infections
- Promote breastfeeding [2,3]
- Promote cessation of maternal & household smoking [3,4]

[1] Garegnani et al. Cochrane Review, 2021 https://doi.org/10.1002/14651858.CD013757.pub2 ; [2] Mineva et al. BMJ Global Health, 2023 http://dx.doi.org/10.1136/bmjgh-2022-009693 ; [3] Shi et al. Journal of Global Health, 2015 doi: 10.7189/jogh.05.020416; [4] Homaira et al. BMJ Open, 2016 http://dx.doi.org/10.1136/bmjopen-2016-011398 ; [6] Le et al. Vaccine, 2023 https://doi.org/10.1016/j.vaccine.2023.06.085

Immunisation Coalition Art Prize Winner 2023 “Keep your hand clean” by Linh Dinh 8, Queensland. https://www.immunisationcoalition.org.au/2023-art-prize-winners/

Thank You!

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Questions

www.immunisationcoalition.org.au

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- Huge thank you to Dr Saravanos as well as the audience for their engagement and questions.
- Gemma's slides and a recording will be made available on the IC website next week.
- Next IC webinar: 10th July on pneumococcal disease. Visit the IC website under Events/Webinars to register.
- The Evaluation Form you should already have in your inbox, and we look forward to hearing your feedback to ensure future presentations continue to be of a high quality.

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