RSV in hematology patients: disease burden and prevention

ANZTCT Lunch ’n’ Learn

Sponsored by Pfizer

31 August 2026

Today's Agenda

Introduction

Presentation – *Dr. Tina Marinelli*

Fireside Chat – *Prof. Andrea Henden (Facilitator)*

Safety Reminders

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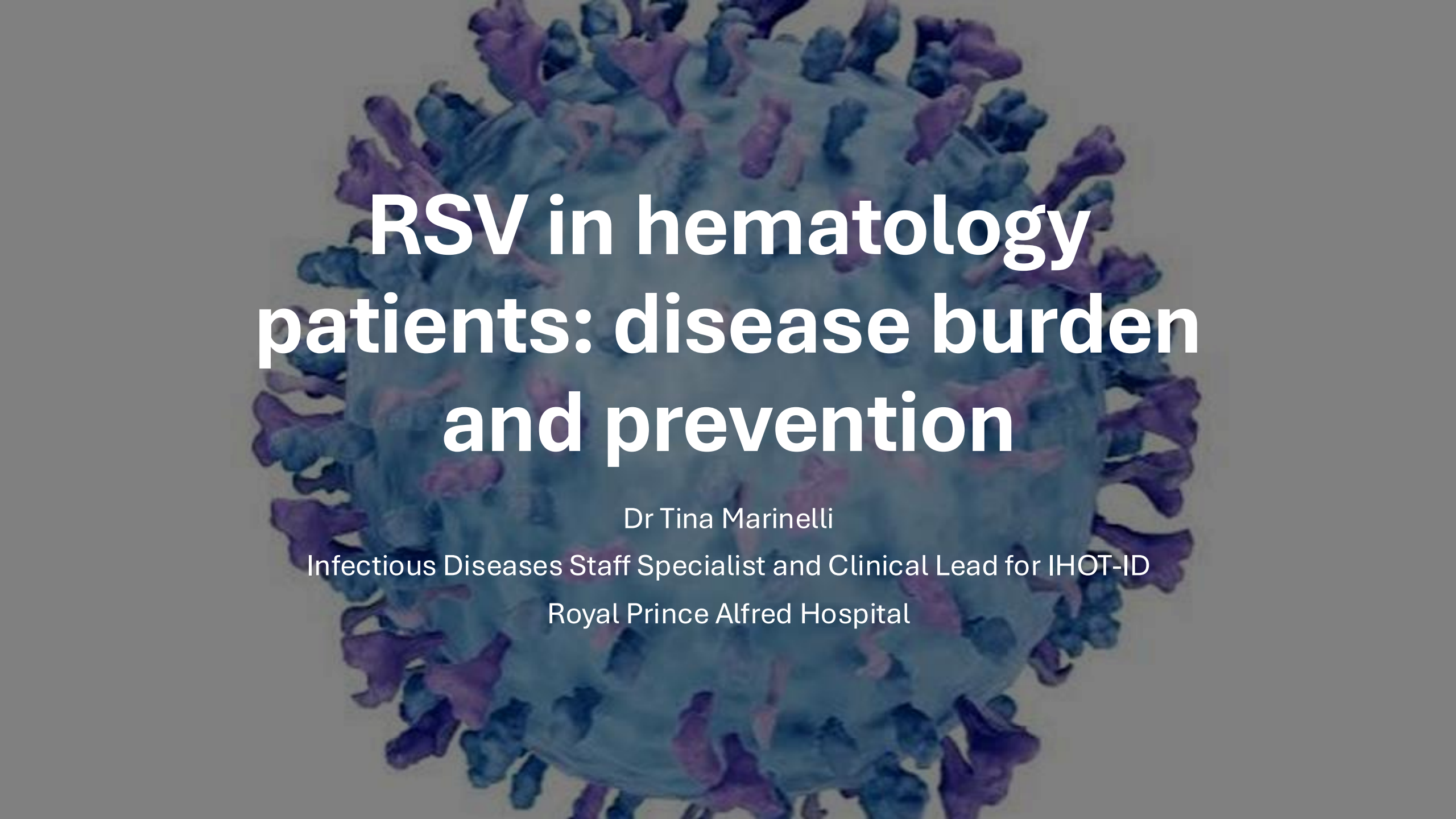
Our Speaker

Tina Marinelli

Dr Tina Marinelli is an infectious diseases staff specialist at RPA, Sydney, where she leads the immunocompromised infectious diseases service.

She is the incoming chair of the Transplant Society of Australia and New Zealand Transplant Infectious Diseases Special Interest Group and a Senior Clinical Lecturer at the University of Sydney.

She is involved with writing guidelines for several national and international societies and her research interests focus on prevention of infection in immunocompromised hosts.



RSV in hematology patients: disease burden and prevention

Dr Tina Marinelli

Infectious Diseases Staff Specialist and Clinical Lead for IHOT-ID

Royal Prince Alfred Hospital

Disclosures

Related to this presentation

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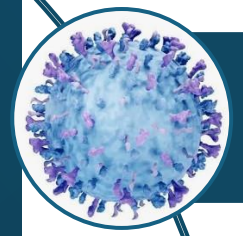
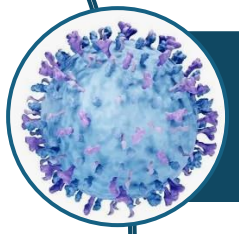
- Astra Zeneca – PI of industry funded study

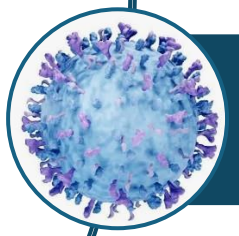
Overview



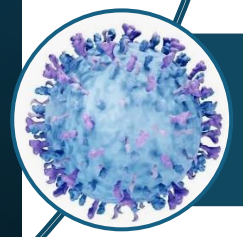
Community acquired respiratory viruses (CARVs) - epidemiology



RSV and other CARVs in hematology

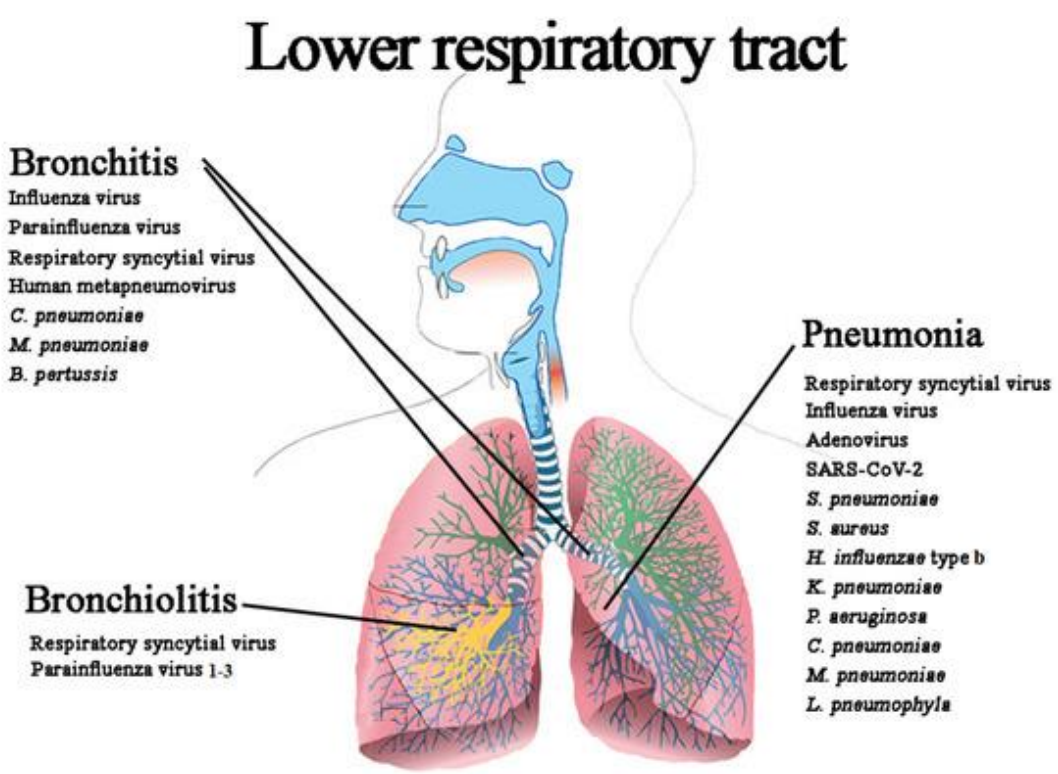


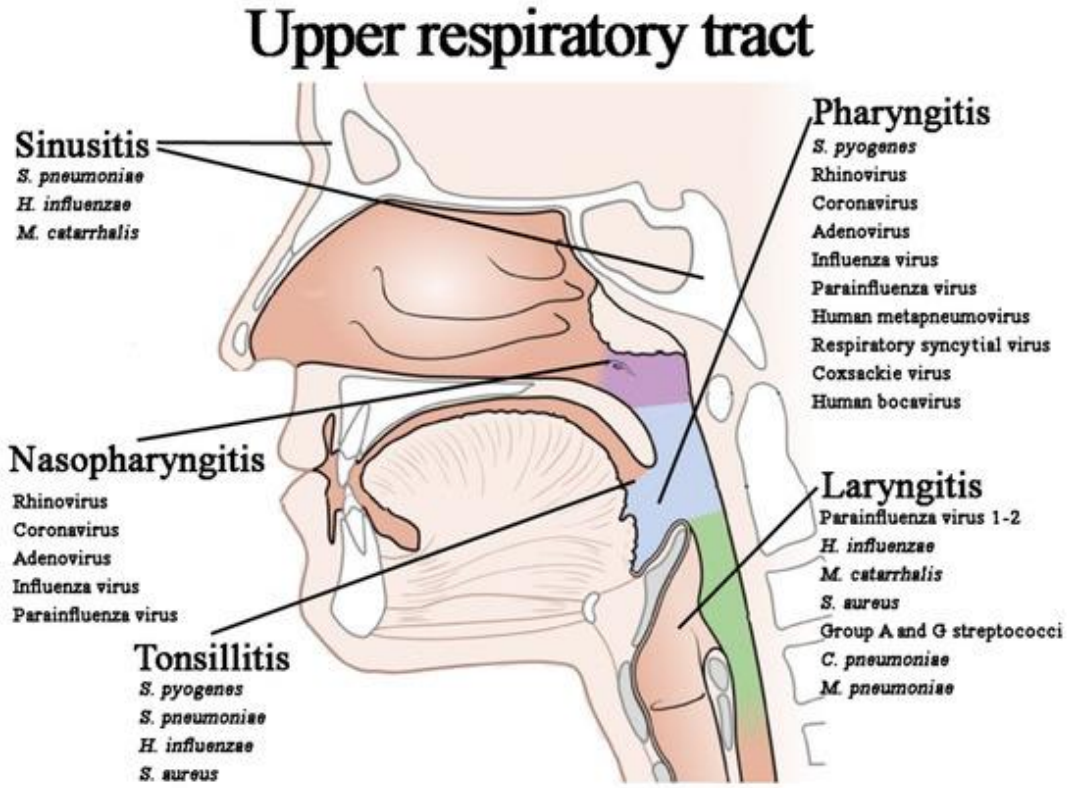
Treatment of RSV



Prevention of RSV - vaccination

Respiratory pathogens





Calderaro. Microoganisms. 2022

Influenza vs RSV vs other community acquired respiratory viruses (CARV)

Symptoms	COLD	FLU	RSV
Cough	✓	✓	✓
Blocked or runny nose	✓	✓	✓
Fever	Sometimes	✓	✓
Sore throat	✓	✓	
Body ache		✓	
Headache	✓	✓	
Diarrhoea or vomiting		✓	
Feeling hot or cold		✓	
Shivering		✓	
Red eyes	✓		
Fatigue		✓	
Wheezing			✓
Seizures		Rare	
Earache		✓	
Complications	Most children will not have complications from a cold	Symptoms can be more severe than a cold	Can cause severe illness such as bronchiolitis or pneumonia

No pathognomonic clinical syndrome thus laboratory testing is crucial to allow early intervention and/or treatment

https://www.healthdirect.gov.au/respiratory-syncytial-virus-rsv

CARV diagnostics, then and now

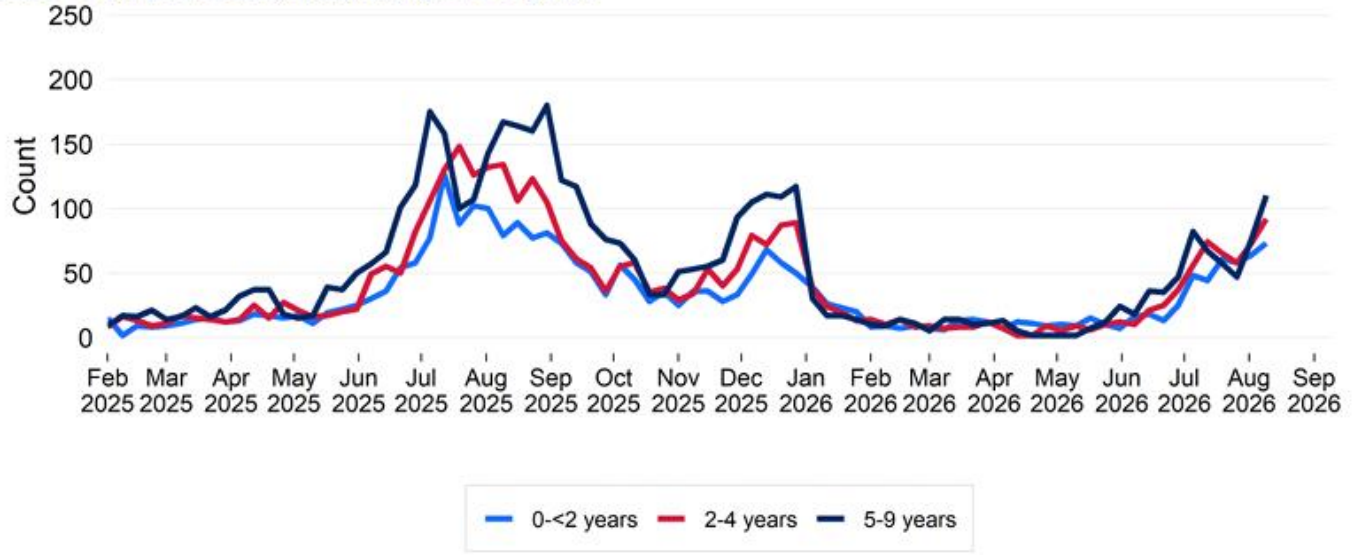
Traditional/early methods	The molecular revolution	Decentralization and genomic surveillance
Viral culture Direct fluorescent antibody testing	PCR - Single-plex - Multiplex - Real-time	Point of care testing In home testing Next generation sequencing

CARVs are unavoidable

Various stock images from Google search

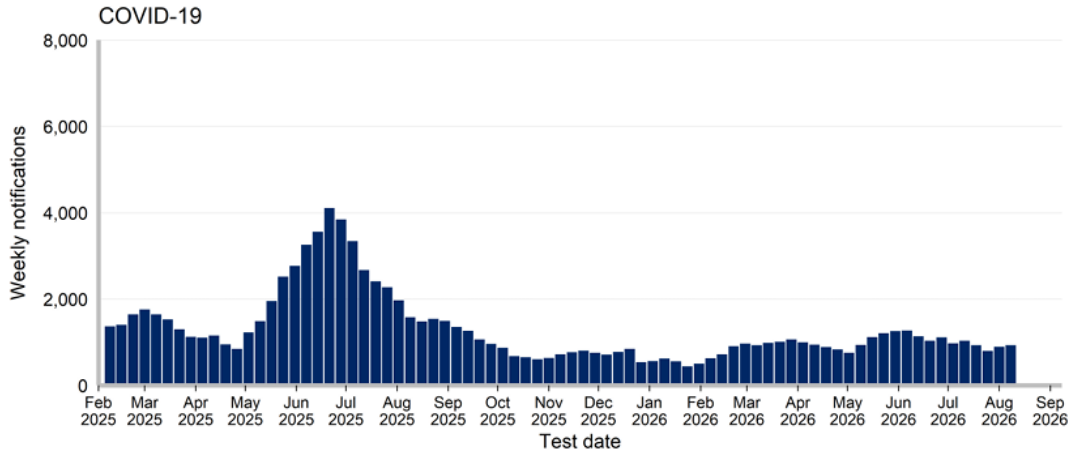
‘Influenza-like illness’

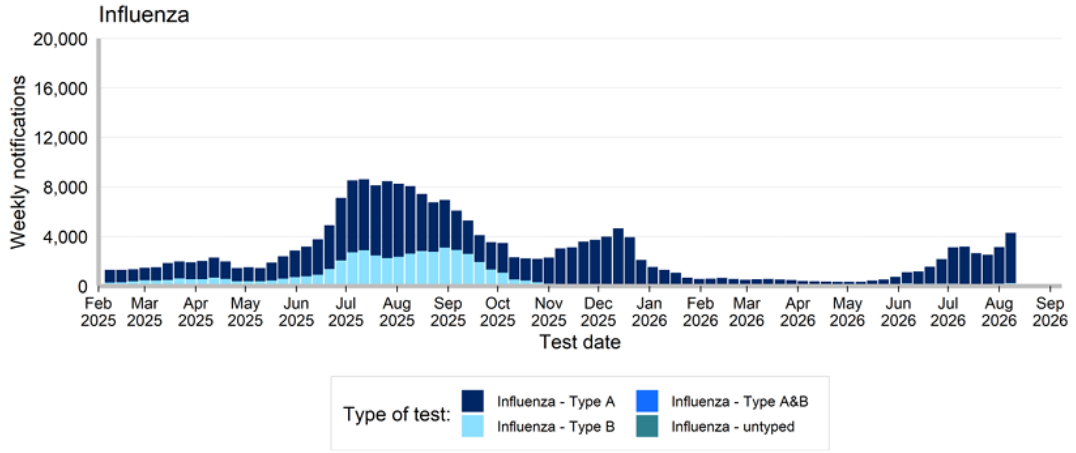
Figure 3. ‘Influenza-like illness’ weekly counts of unplanned emergency department (ED) presentations, 1 February 2025 - 9 August 2026, children aged 0-9 years

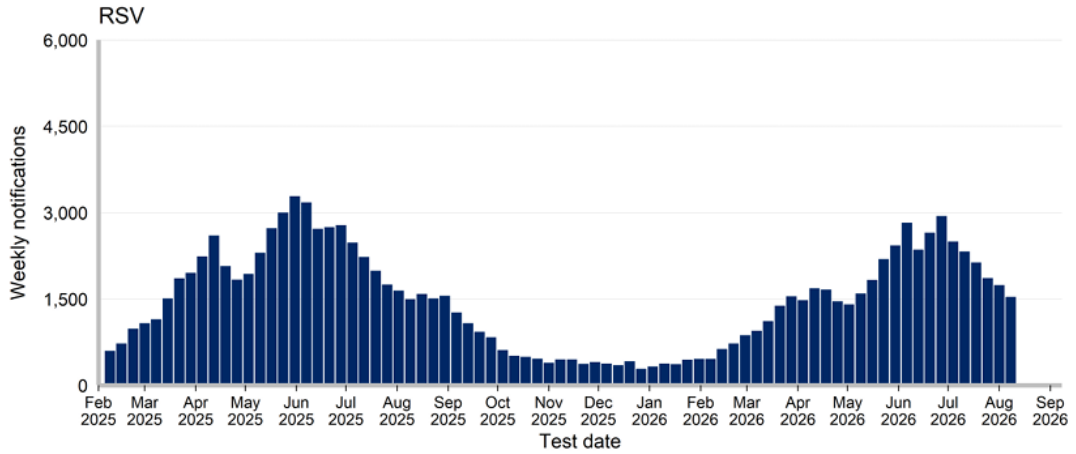


respiratory-surveillance-20260808.pdf

Epidemiology of CARVs in NSW







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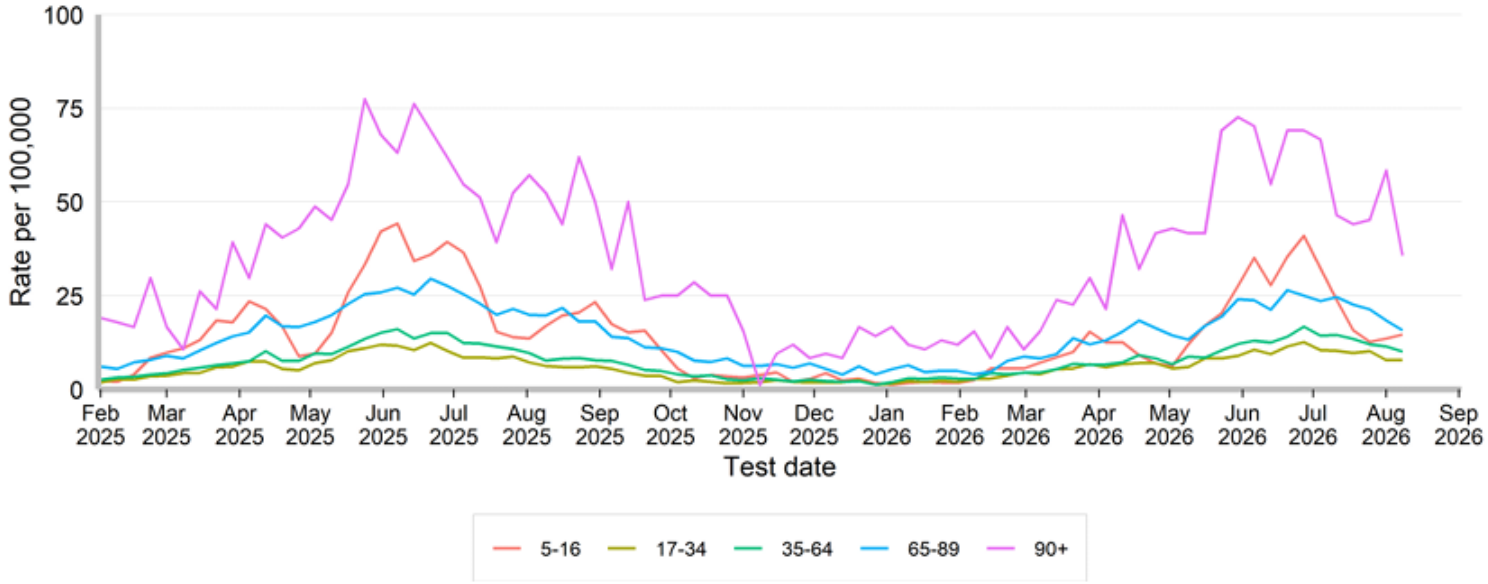
Rates of RSV across age groups

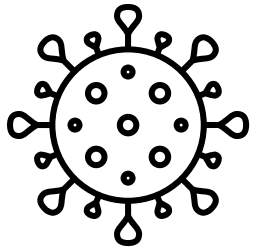


RSV epidemiology in hematology patients mirrors the general population

respiratory-surveillance-20260808.pdf

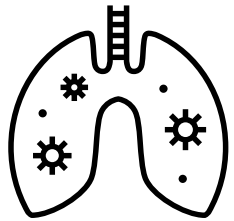
CARVs in the ICH: a delicate balance between immune control of virus and immune stimulation

Inoculum of virus



Intrinsic pathogenicity of virus

Overall number of immune effector cells (Quantity)



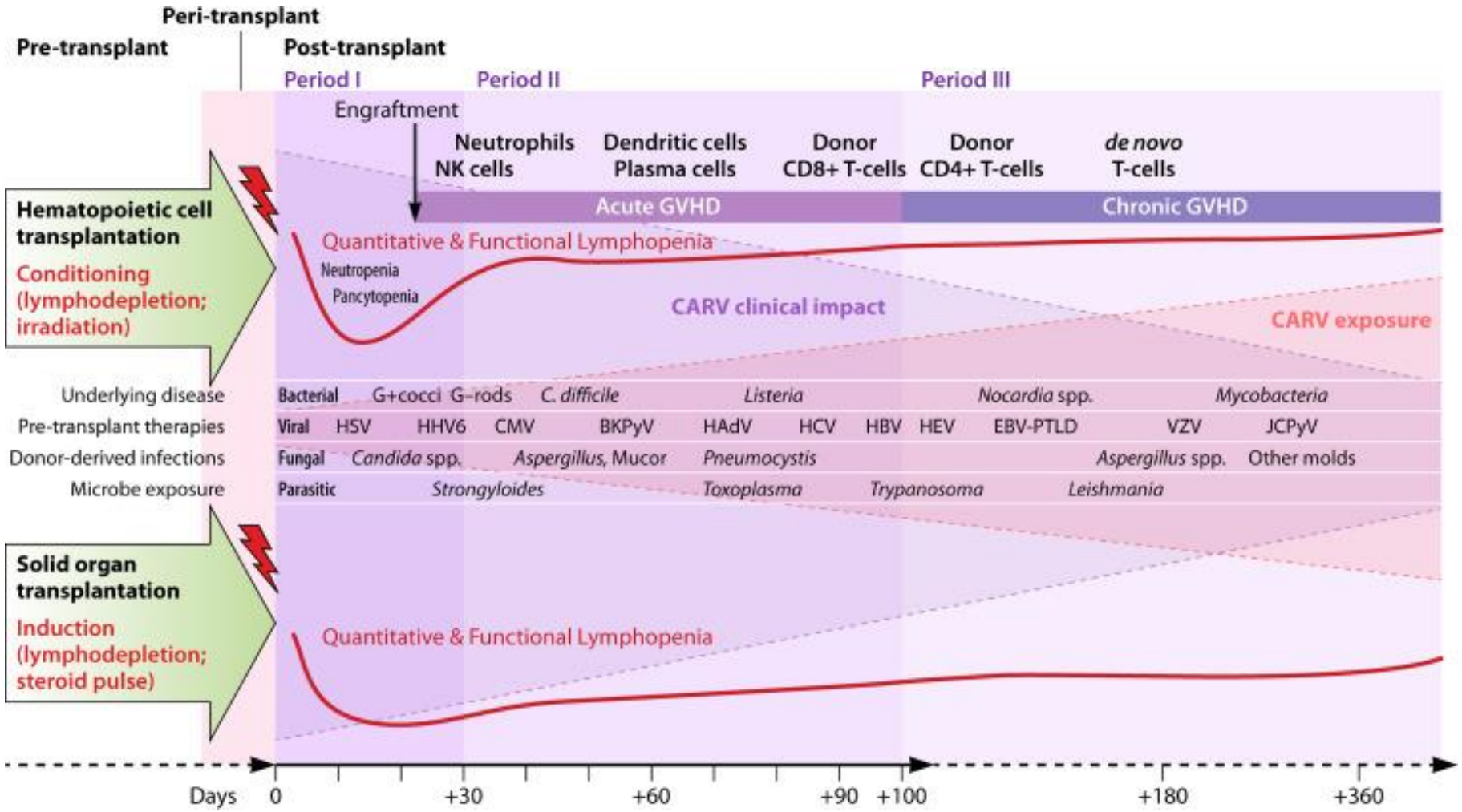
Effectiveness of immune response (Quality)

Impaired immune response

Inflammatory (allo-) immune response

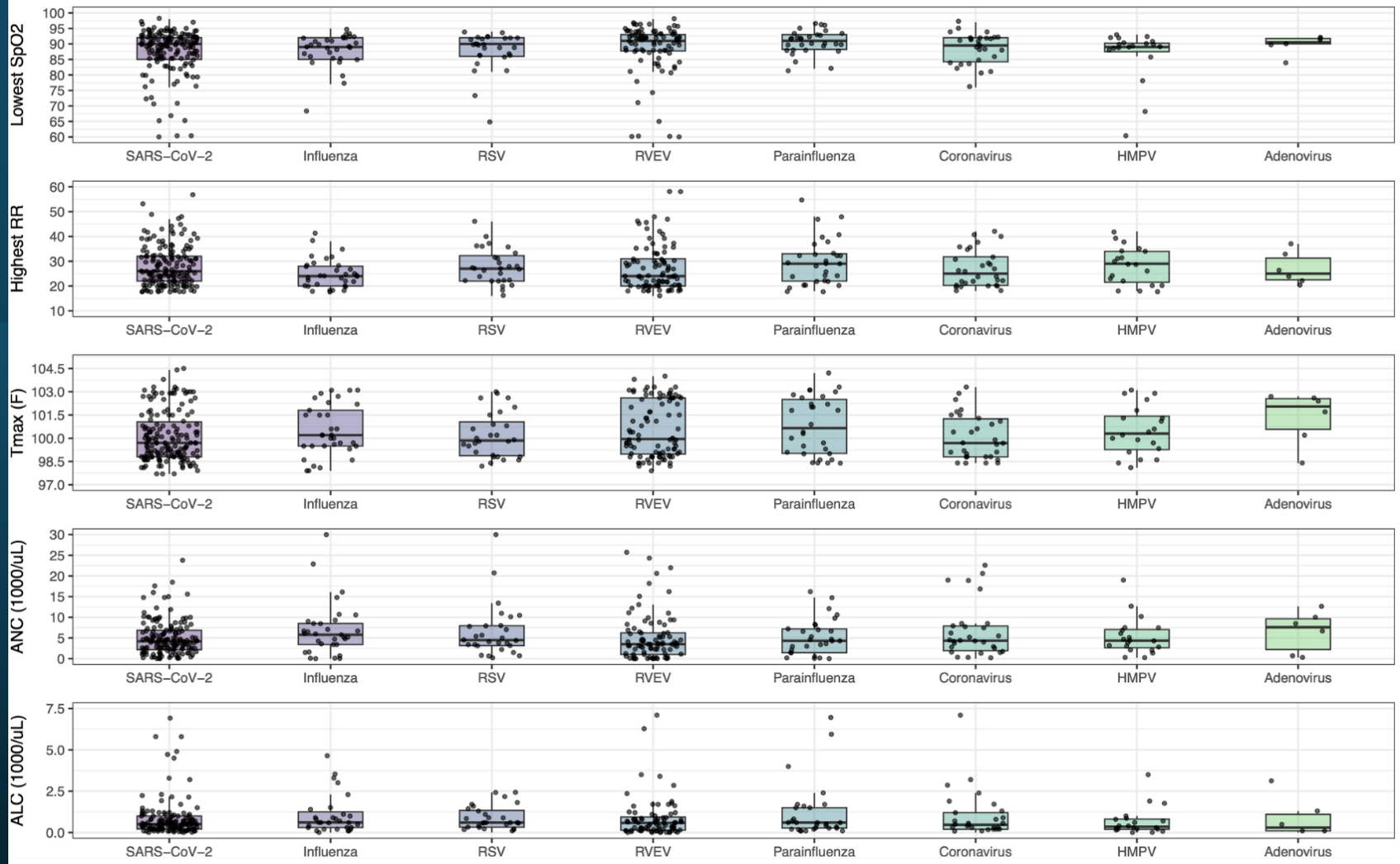
Hirsch. Transpl Infect Dis. 2005

Impact of CARV infection in immunocompromised hosts



Ison. Clin Microbiol Rev. 2019

CARV in hematology patients



No pathogen-specific differences in initial presentation

Lokhandwala. Open Forum Infect Dis. 2025

Management of RSV

	SARS-CoV-2 (n=162)	Influenza (n=33)	RSV (n=28)	Rhino-enterovirus (n=92)	Parainfluenza (n=30)
Antivirals	53%	85%	36%	0%	0%
Antibiotics	60%	67%	61%	64%	73%
Corticosteroids	61%	27%	36%	33%	17%

Lokhandwala. Open Forum Infect Dis. 2025

Risk of progression of RSV to lower respiratory tract infection in HCT recipients is 30-60%

Immune cell parameters*	HCT factors	Patient factors
• Neutropenia <500 cells/mL • Lymphopenia <200 cells/mL	• HCT <1 year • Myeloablative chemotherapy <1 year • GVHD • Steroid use • MUD HCT • Prior auto-HCT • Cord blood HCT	• >40 years • Smoker • Nosocomial infection

Red = components of the Immunodeficiency Scoring Index

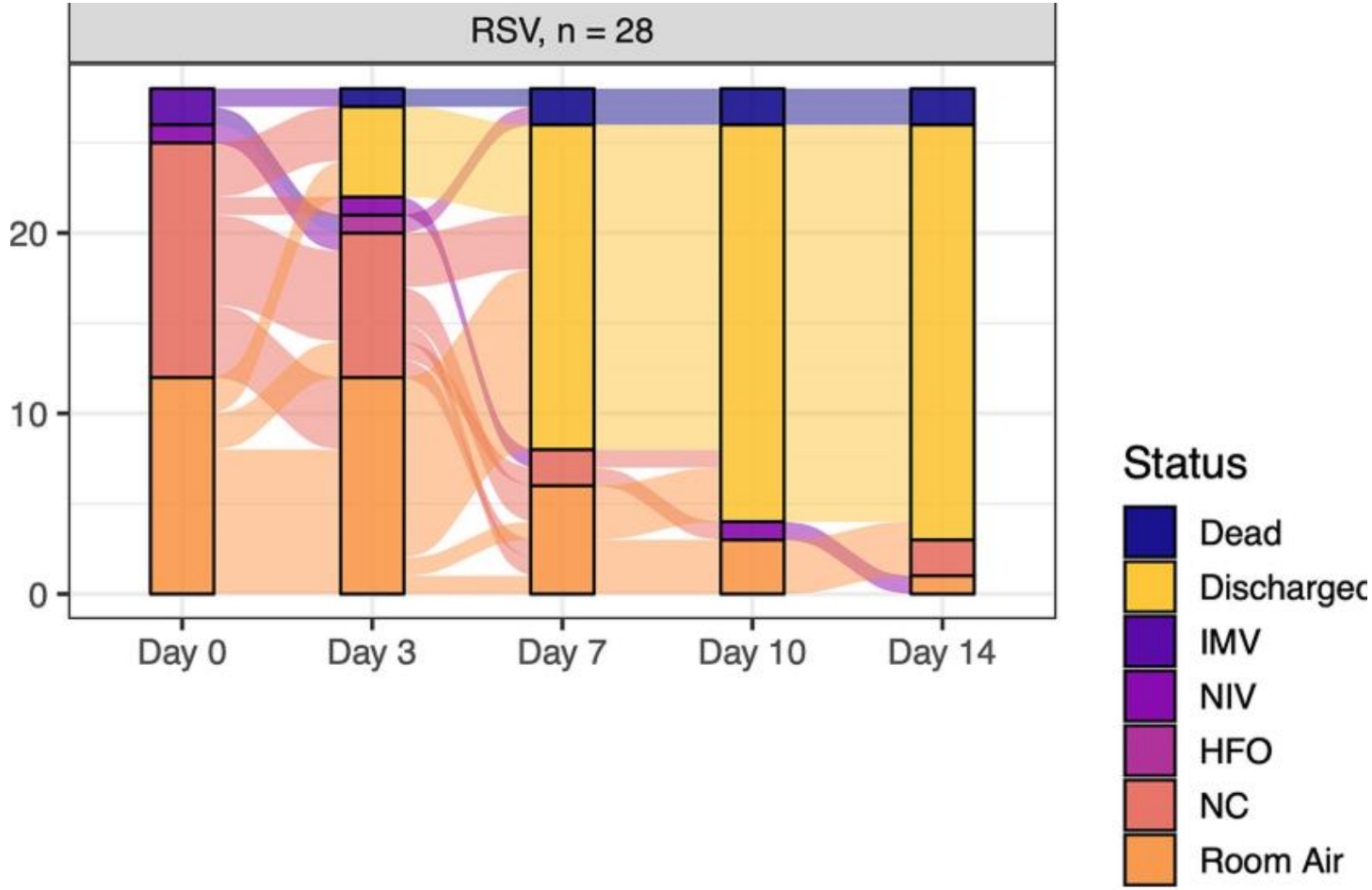
Khawaja. Hematologica. 2019

CARV – Patient Outcomes

	SARS-CoV-2 (n=162)	Influenza (n=33)	RSV n=28)	Rhino-enterovirus (n=92)	Parainfluenza (n=30)
ICU admission	27%	36%	21%	28%	33%
High flow oxygen	20%	18%	7.1%	8.7%	17%
Non-invasive ventilation	15%	27%	18%	14%	30%
Invasive ventilation	14%	15%	11%	8.7%	10%
Death	15%	15%	11%	7.6%	0%
Discharge to hospice	3.1%	0%	0%	22%	3.3%

Lokhandwala. Open Forum Infect Dis. 2025

RSV severity over time



Lokhandwala. Open Forum Infect Dis. 2025

RSV complications

Infectious

RSV URTI

Non-infectious

RSV LRTI

Secondary bacterial infections

- *Staphylococcus aureus*
- *Streptococcus pneumoniae*
- *Pseudomonas aeruginosa*
- *Moraxella catarrhalis*
- *Haemophilus influenzae*

Secondary fungal infections

Death

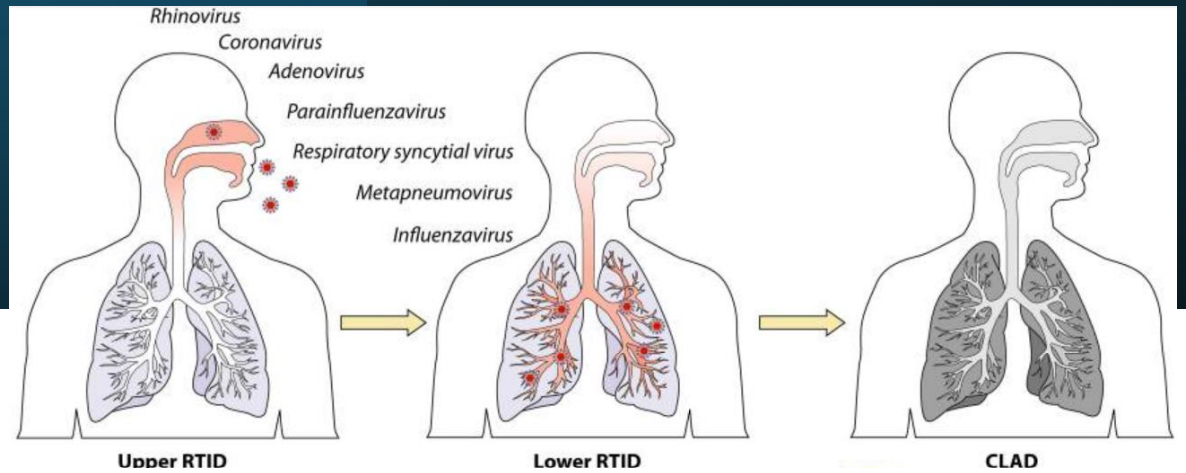
? Delayed engraftment

Reduction in pulmonary function

Bronchiolitis obliterans

Khawaja. Hematologica. 2019

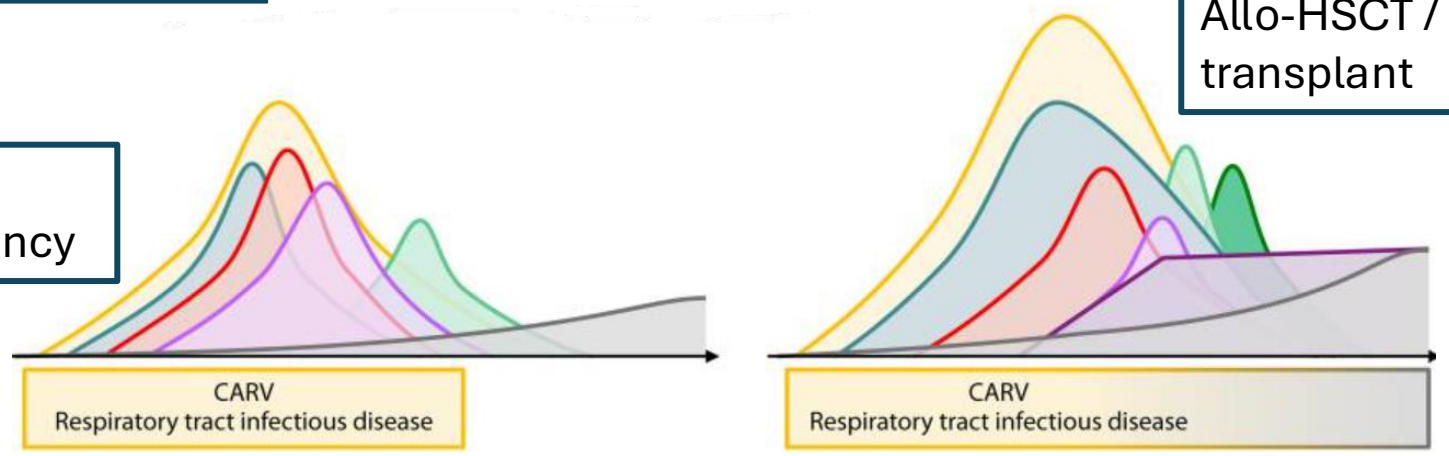
Is it the CARV or the immune system that causes lung damage?



Relative level and intensity of direct CARV cytopathology and adaptive immune response

No/moderate immunodeficiency

Allo-HSCT / Lung transplant



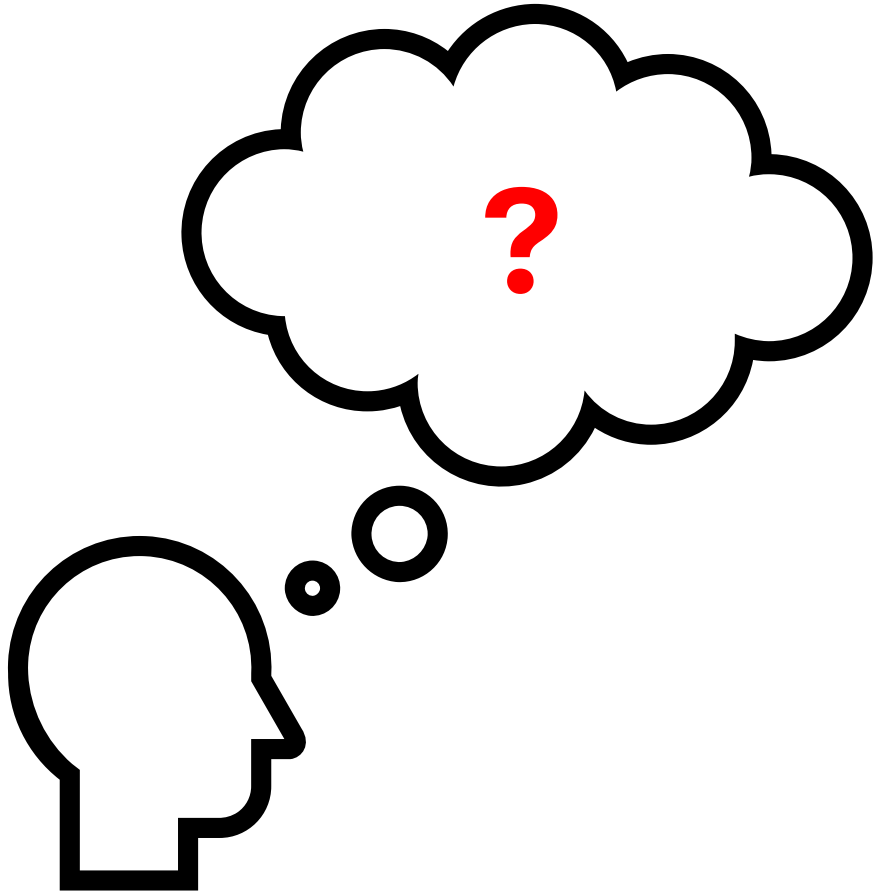
CARV (respiratory tract infectious disease)
Cytopathology/Direct virus damage
Inflammation/"innate immunity"/Alarm and initial containment
Inflammation/"adaptive immunity"/Antigen clearance
Bacterial superinfection
Fungal superinfection
Rejection: Acute–Chronic (BOS/CLAD)
Fibrosis

Ison. Clin Microbiol Rev. 2019

RSV treatment

- No large, prospective RCTs

- Agents used:
  - Ribavirin (PO/IV)
  - Standard IVIg
  - High-titre RSV IVIg
  - Palivizumab



von Lilienfeld-Toal. Lancet. 2026

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RSV-specific treatments in hematology patients

Current ECIL recommendations

Pre-/post-exposure prophylaxis
- Ribavirin should not be used

Systemic ribavirin for RSV in HSCT
- Can be considered if high risk of progression (BIIu)
- Don’t use if low risk of progression

Aerosolized ribavirin
- Can be considered (BIIu)
- +++ logistical and toxicity considerations

Adjunctive measures
- IVIg can be considered in those with high risk of progression or hypogammaglobulinemia
- Corticosteroids >1mg/kg has been associated with poorer outcomes

von Lilienfeld-Toal. Lancet. 2026

Treatments in this slide may not be approved for use in Australia for the suggested indications.
Pfizer does not recommend the use of any product in a manner other than as described in the product information.

Prevention of RSV

Pathogen avoidance

- Single rooms + other infection control measures
- Strict management of sick hospital staff
- Mask wearing
- Avoidance of visitors

Passive immunisation

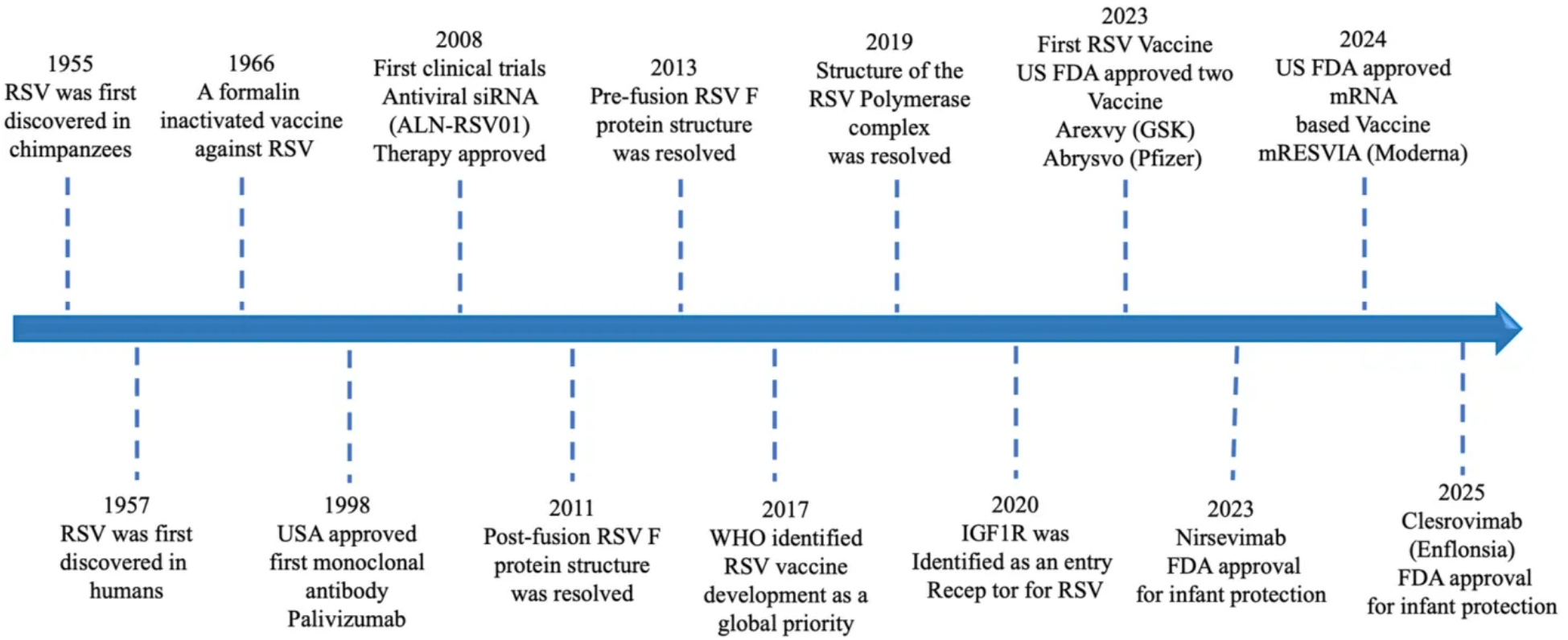
- Pre-exposure prophylaxis for children <2y/o
  - Palivizumab (short-acting)
  - Nirsevimab (long-acting)

Active immunisation

- Abrysvo (RSVpreF; Pfizer) (Pregnant Women, ≥ 60 years)
- Arexvy (RSVPreF3OA; GSK) (High-risk 50-59 years, ≥ 60 years)

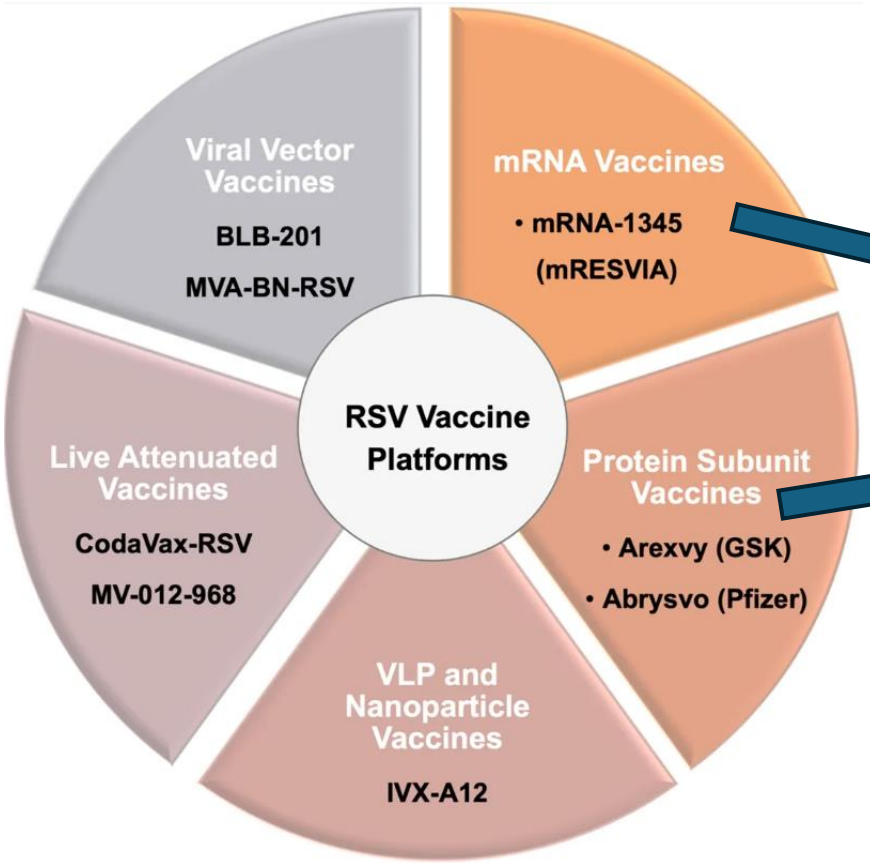
Refer to the Australian Immunisation Handbook for full details

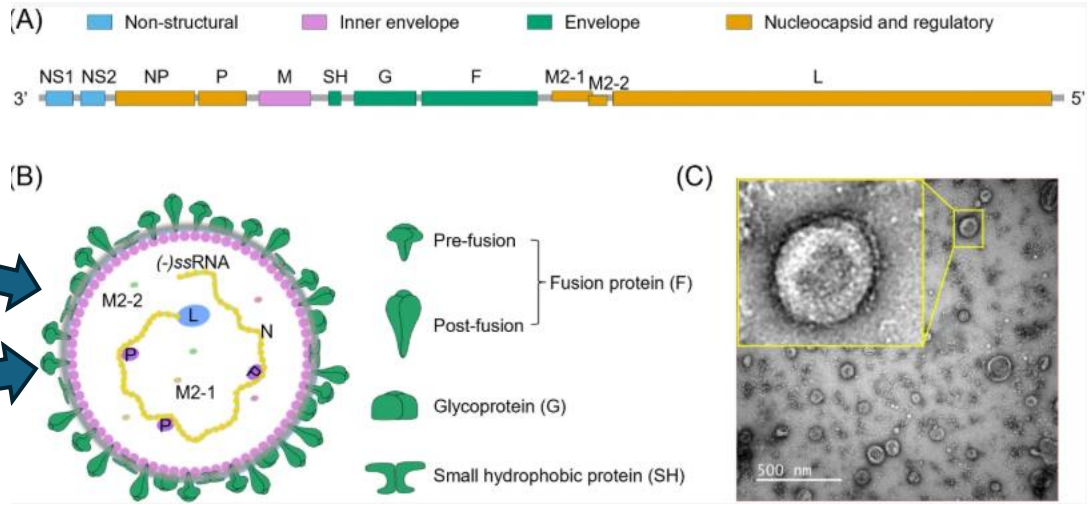
Why has it taken so long to develop an RSV vaccine?



Xu. Front Immunol Viral Immunol. 2026

RSV Vaccines





Xu. Front Immunol Viral Immunol. 2026

The RSV vaccine landscape in Australia

AIH recommends RSV Vaccination:

- Pregnant women to protect their newborn infant
- All people aged ≥75 years and Aboriginal and Torres Strait Islander people aged ≥60 years
- People with medical risk factors for severe RSV disease aged ≥60 years.

Vaccine	Approval Date	TGA approval	NIP funding
Arexvy (GSK)	January 2024	≥ *60 years* 50 to 59 years who are at increased risk for RSV infection	All adults ≥ *75 y/o* *ATSI* ≥ *60 y/o*
Abrysvo (Pfizer)	March 2024	≥ *60 years** Pregnant women 24-36 weeks gestation	Pregnant women

*TGA application for individuals ≥ *18 years*

www.tga.gov.au
Respiratory syncytial virus (RSV) | The Australian Immunisation Handbook

RSV Vaccine RCTs in older adults

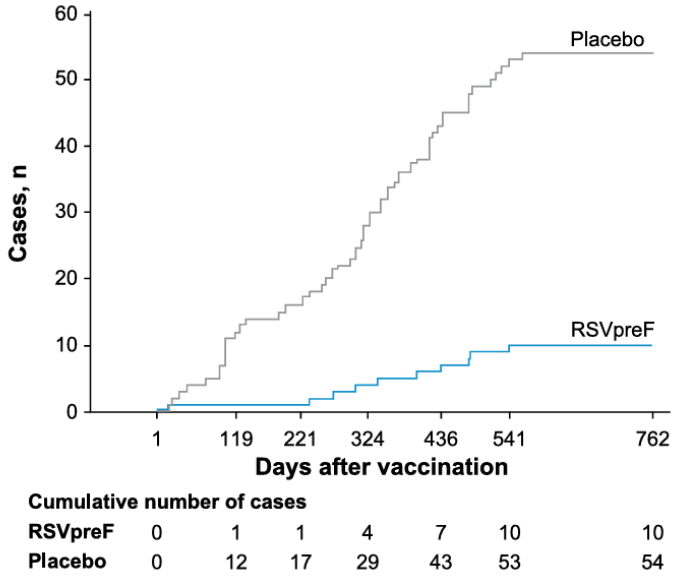
Walsh. N Eng J Med. 2023
Walsh. Clin Infect Dis. 2025
Papi. N Eng J Med. 2023
Ison. Lancet Resp Med. 2025

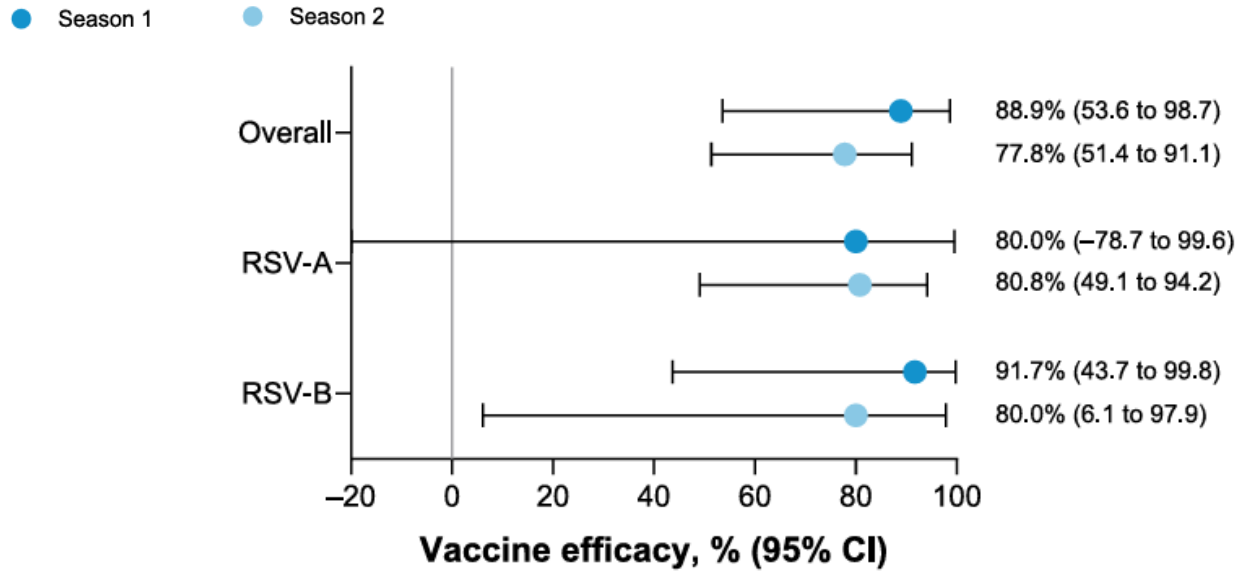
	RENOIR (Abrysvo)	AReSVi-006 (Arexvy)
Design	Phase 3, multicentre, randomized, double blind, placebo-controlled	Phase 3, multicentre, randomised, placebo-controlled, observer-blind
Inclusion	≥60, healthy/stable medical conditions	≥60, healthy/stable medical conditions
Exclusion	Immunocompromised persons (apart from stable HIV)	Immunocompromised persons
Intervention	1:1 vaccine or placebo	1:1 to vaccine or placebo
Primary outcome	Efficacy: prevention of 1st RSV-LRTI in the 1st season post-vaccination *Vaccine efficacy against seasonal RSV-associated lower respiratory tract illness with at least two or at least three signs or symptoms*	Efficacy: prevention of 1st RSV LRTI in the 1st season post-vaccination *Vaccine efficacy against RSV-related lower respiratory tract disease defined as at least two lower respiratory symptoms or signs or at least three lower respiratory symptoms lasting for at least 24 hours*
Secondary outcomes	Efficacy: prevention of first RSV-LRTI in 2nd season post-vaccination Immunogenicity: RSV preF-elicited immune responses	Efficacy: prevention of RSV-LRTI over 3 seasons following a single dose and two doses (2nd dose given 12 months after first)

RENOIR (Abrysvo)

- August ‘21 – December ‘23
- 36,862 participants
- Median age 67 y/o
- 52% had ≥ high risk condition

Walsh. N Eng J Med. 2023
Walsh. Clin Infect Dis. 2025



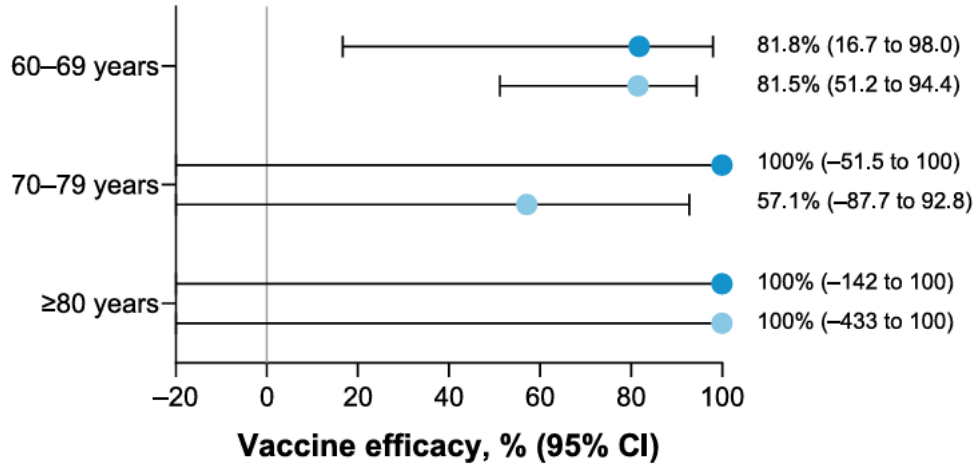


Cumulative distribution curve of lower respiratory tract illness associated with respiratory syncytial virus (RSV-LRTI) cases with ≥3 symptoms through 2 RSV seasons

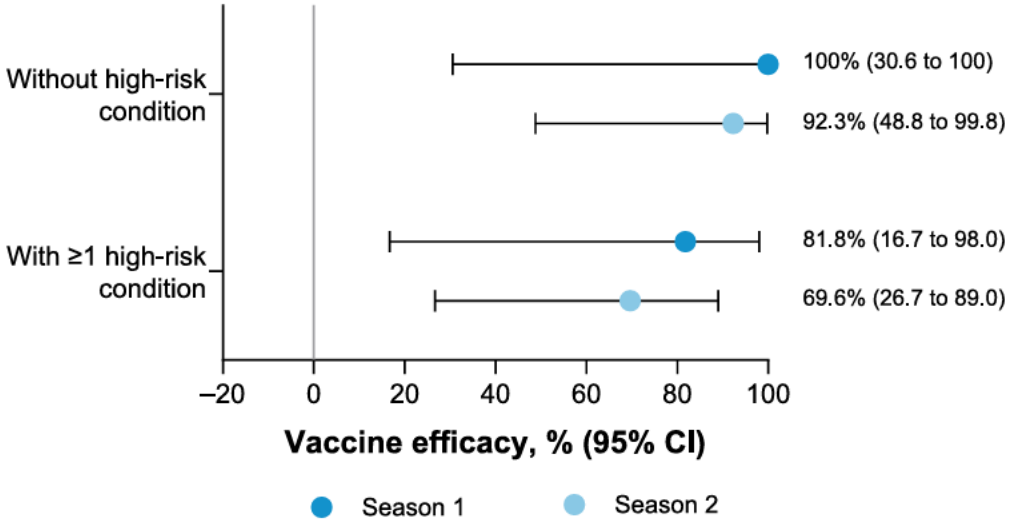
RSVpreF effectively prevented the first RSV-LRTI episode with ≥3 symptoms throughout 2 seasons

Walsh. N Eng J Med. 2023
Walsh. Clin Infect Dis. 2025

RENOIR (Abrysvo)



Vaccine efficacy for first episode of RSV-LRTI with ≥3 symptoms in the first and second RSV season overall and stratified by RSV subgroup



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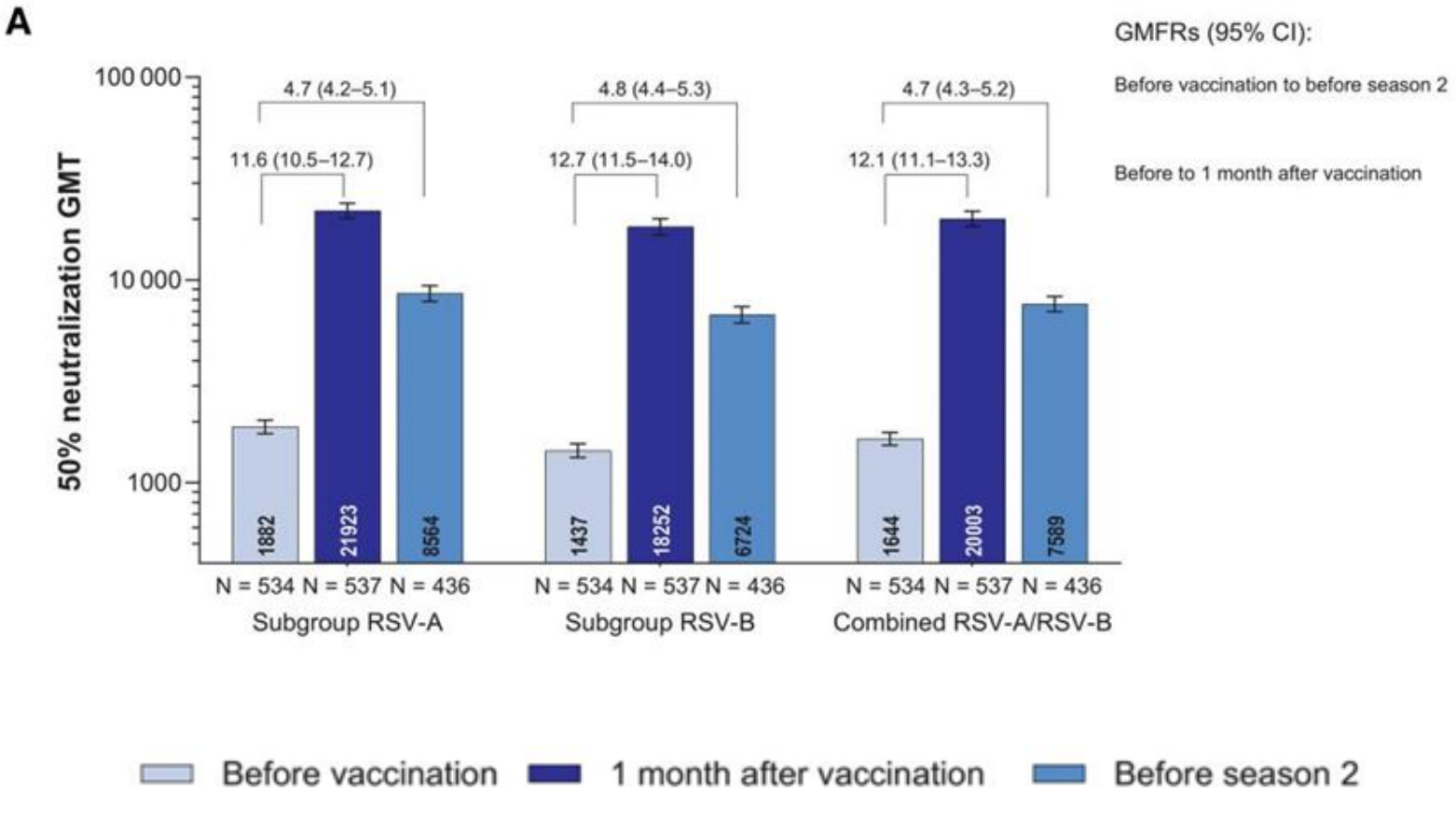
Walsh. N Eng J Med. 2023
Walsh. Clin Infect Dis. 2025

RENOIR (Abrysvo)

Immunogenicity subset n = 1151 participants



Neutralizing GMTs for the RSVpreF group were substantially increased from before to 1-month post-vaccination for RSV-A and RSV-B and for RSV-A and RSV-B combined

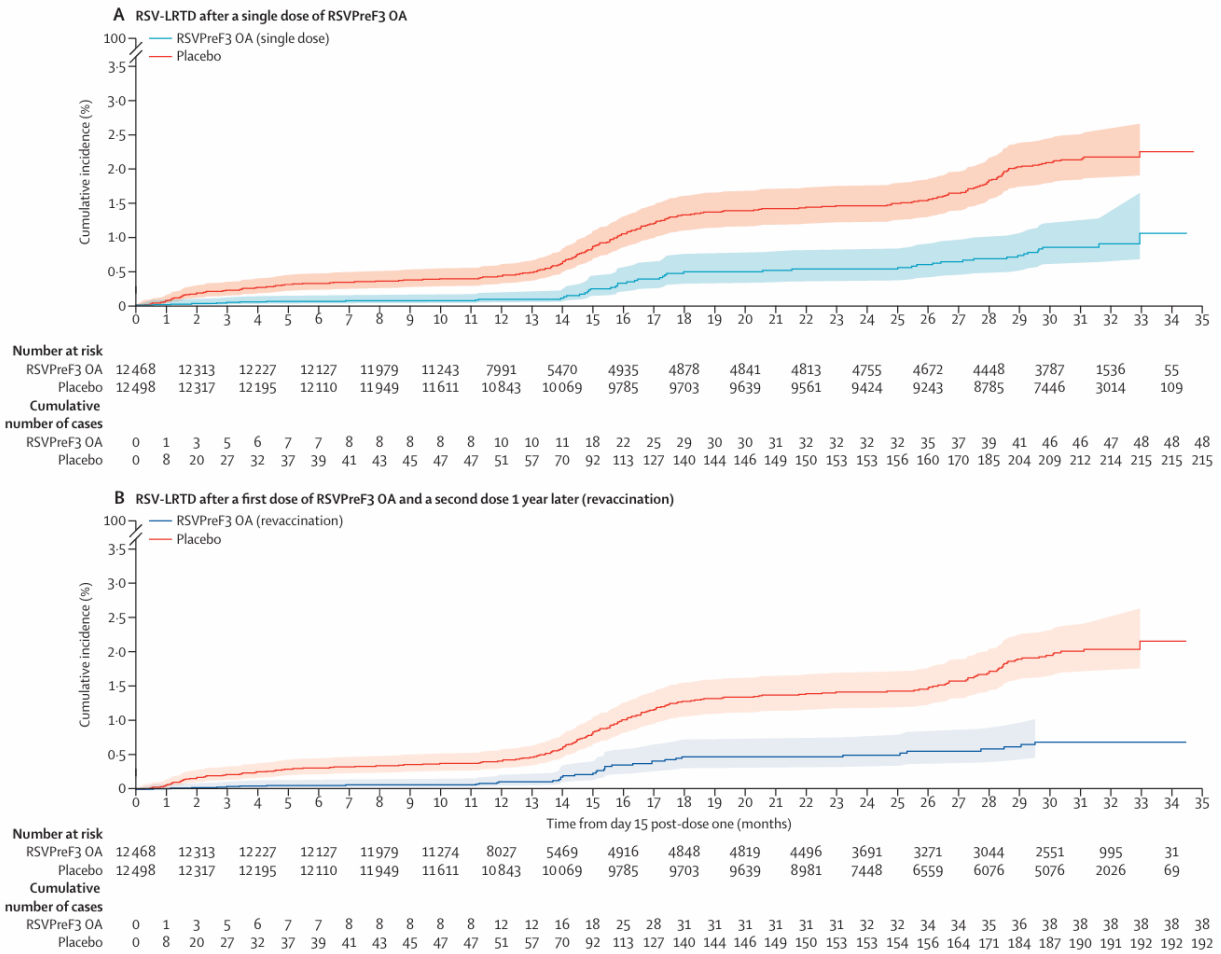
At the preseason 2 visit (occur ring from 8–20 months post-vaccination), neutralizing GMTs decreased but remained substantially higher than baseline.

AReSVi-006 (Arexvy)

- May ’21 – May ‘24
- 24,972 participants
- 12 469 received vaccine, 5000 received a 2nd dose
- Mean age 69.5 years
- 40%had ≥ high risk condition

Papi. N Eng J Med. 2023
Ison. Lancet Resp Med. 2025

Cumulative incidence of RSV over 3 seasons

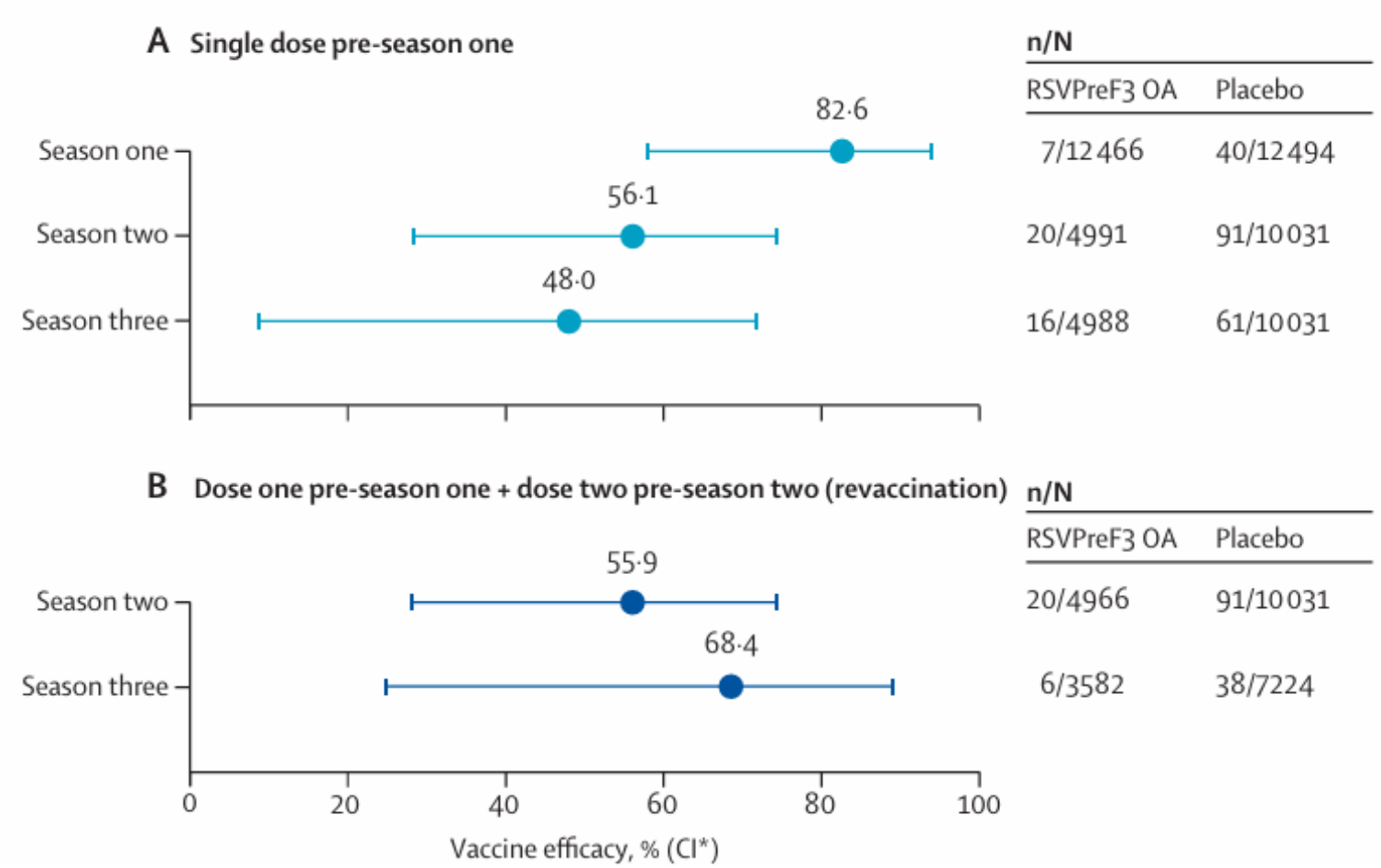


Cumulative efficacy of a single RSVPreF3 OA dose in preventing RSV-LRTD over three RSV seasons was 62·9% (97·5% CI 46·7–74·8)

Vaccine efficacy of the revaccination regimen in preventing RSV-LRTD over three RSV seasons post-dose one was shown for RSV-LRTD due to either subtype (67·8% [97·5% CI 51·8–79·1])

Papi. N Eng J Med. 2023
Ison. Lancet Resp Med. 2025

AReSVi-006 (Arexvy)



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Safety analysis

Walsh. N Eng J Med. 2023
Walsh. Clin Infect Dis. 2026
Papi. N Eng J Med. 2023
Ison. Lancet Resp Med. 2025
Saif-Ur-Rahman. Cochran Data Syst Rev. 2025
Melgar. CDC. 2024
https://www.tga.gov.au/

No significant safety concerns identified in RENOIR and AReSVi-006

Cochrane review

- 14 studies (including 5 RCTs)
- No difference in any unsolicited adverse events between RSV prefusion vaccination and placebo in older adults (RR of 1.08 (95% CI 1.04 to 1.12; 3 RCTs, 51, 132 participants; Analysis 1.6).
- No heterogeneity amongst the results (I^2 0%)

Guillan-Barre

US data

- Estimated excess cases of GBS per 1 million doses of vaccine:
  - Abrysvo = 9
  - Arvexy = 7

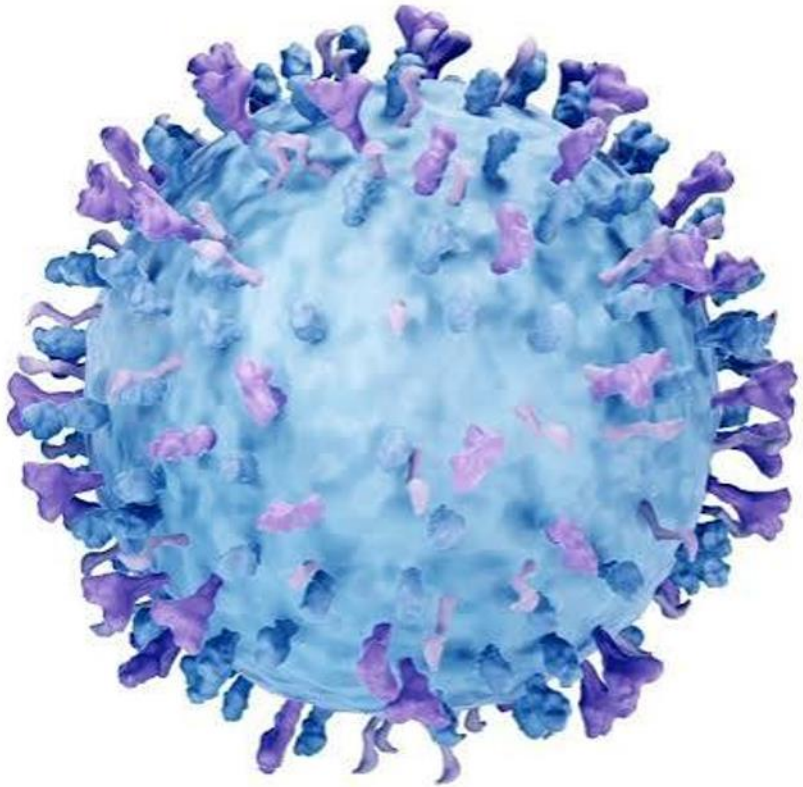
Australia

- Nil cases reported to TGA (as of May 2025)
- GBS included as a risk in PI for both vaccines

Evidence gaps

- Vaccine efficacy in immunocompromised hosts
- Pediatric RSV vaccination
- Duration of vaccine efficacy
- Optimum timing of revaccination
- Global, real-world vaccine efficacy
- RSV monoclonal antibodies for adults

Thank you



Tina.Marinelli@health.nsw.gov.au

Bivalent RSVpreF vaccine effectiveness in the first and second season after vaccination[1,*,†] - *All and Immunocompromised Adults*

Retrospective case-control study (N= 2,235; 767 cases, 1468 controls) with test-negative design during first and second RSV season after vaccination (Season 1: 24 November 2023 - 9 April 2024; Season 2: 5 November 2024 - 21 April 2025) in **US adults aged ≥60 years hospitalised or in ED with an ICD-10 code consistent with LRTD and respiratory specimen collected[‡]**

≥60 Years (all adults)	N: Cases	N: Controls	Median Days Since RSV Vaccination (IQR)	Vaccine Effectiveness[§] RSV-Associated Hospitalisation/ED (95% CI)
First season after vaccination[†]	17	201	84 (52-126)	**81%** (68, 88)
Second season after vaccination[‡]	8	74	372 (342-403)	**75%** (47, 89)

≥60 years IMMUNOCOMPROMISED[+]	Population size	Median Days Since RSV Vaccination	Vaccine Effectiveness RSV-Associated Hospitalisation/ED (95% CI)
First season after vaccination	485	84	**72%** (34, 88)
Second season after vaccination	233	372	**46%** (-69, 83)

[+]Immunocompromise defined as patients with immunocompromising conditions or treatment inc. leukemia, lymphoma, stem cell and organ transplant, metastatic cancer for full details see Tartof et al. 2026
CI, confidence interval; ED, emergency department; RSV, respiratory syncytial virus; US, United States; LRTD, Lower-respiratory tract disease.
[‡]Respiratory specimens tested with multiplex PCR assay for RSV (either SOC testing or enhanced specimen collection of salvaged swabs that were not positive for SARS-CoV-2 or influenza and not already tested for RSV); [§]Retrospective database study using existing healthcare data; no patients were actively enrolled; *First season after vaccination; 2023-2024 season includes those vaccinated October, 2023 to March, 2024 and all unvaccinated with LRTD events in the 2023-2024 season; 2024-2025 season includes those vaccinated April 2024 to March 2025 and all unvaccinated with LRTD events in the 2024-2025 season in the strict analysis population; [†]Includes those vaccinated from October, 2023 to March, 2024 and all unvaccinated with LRTD events occurring during the 2024-2025 RSV season in the strict analysis population; [‡]As described by Gilbert T, et al. 2018.[2]

1.Tartof, S et al. The Lancet Regional Health - Americas, Volume 60, 2026, 101520; 2. Gilbert T, et al. *Lancet.* 2018;391(10132):1775-1782.

Feedback Survey

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