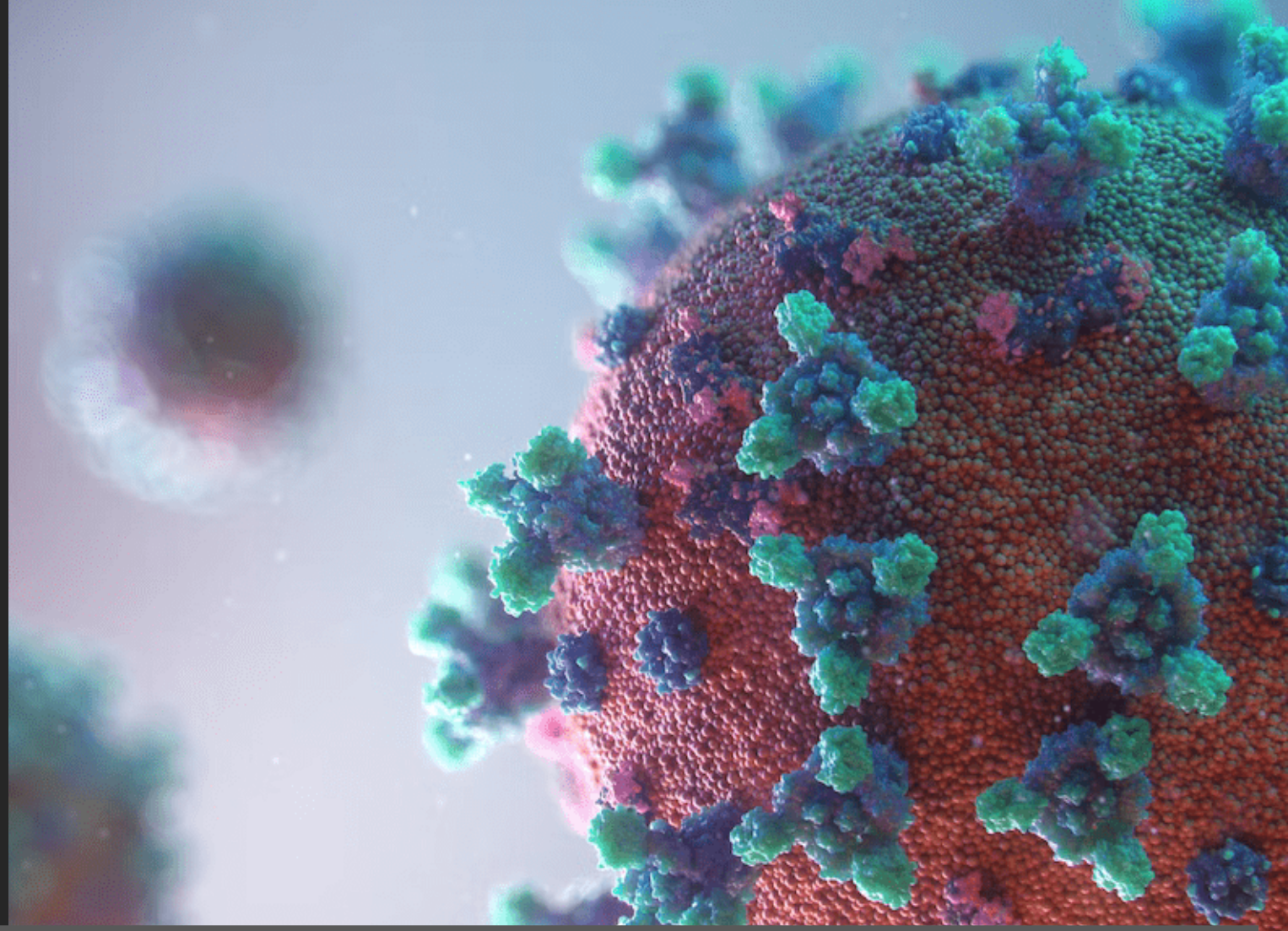
Respiratory Syncytial Virus

Clinical illness, risk factors, treatment and prevention

13th March 2024



Chris Blyth
christopher.blyth@uwa.edu.au
@ChrisBlyth74

Perth Children's Hospital

TELETHON KIDS INSTITUTE
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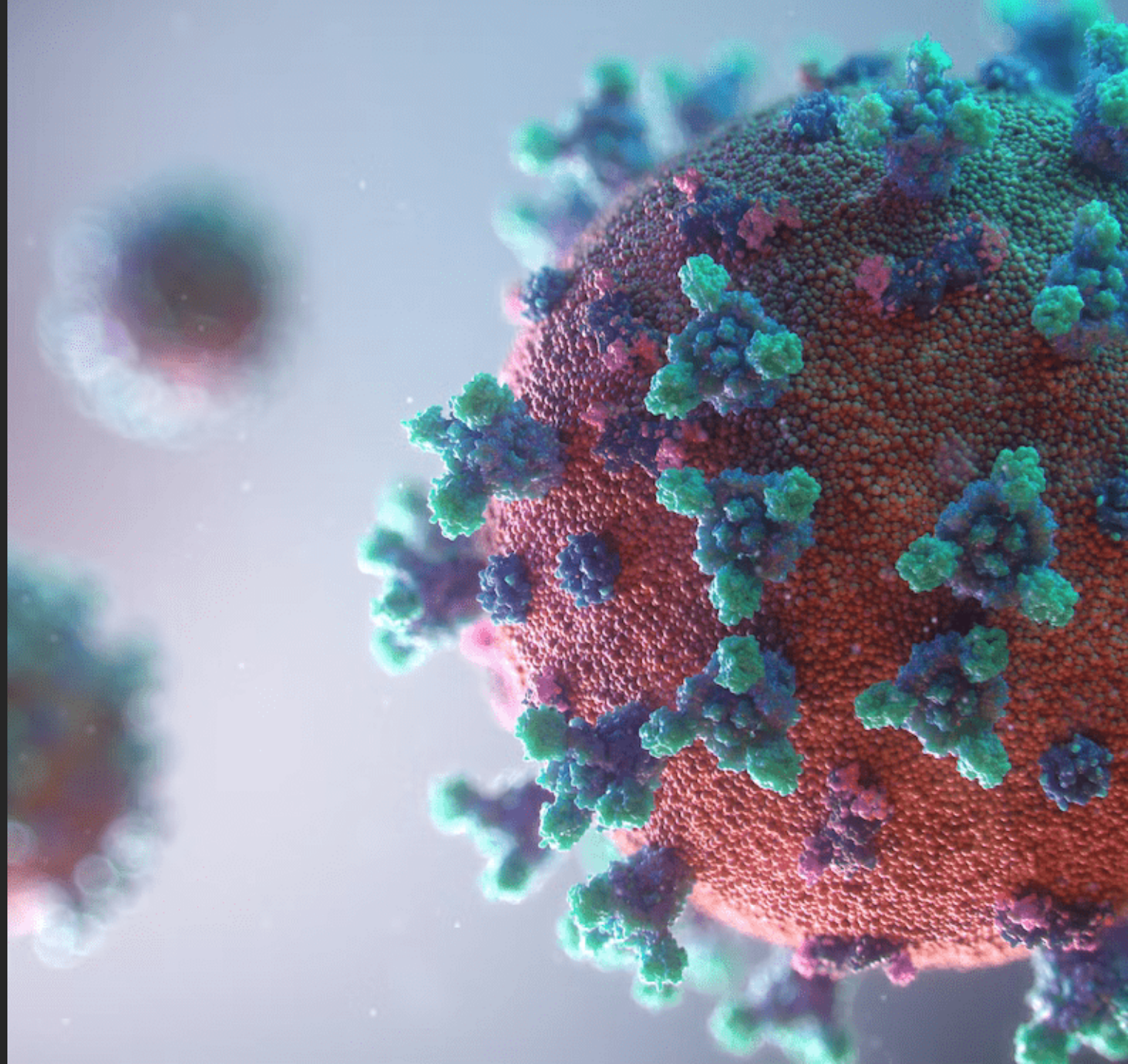
WESFARMERS CENTRE OF VACCINES & INFECTIOUS DISEASES

PathWest

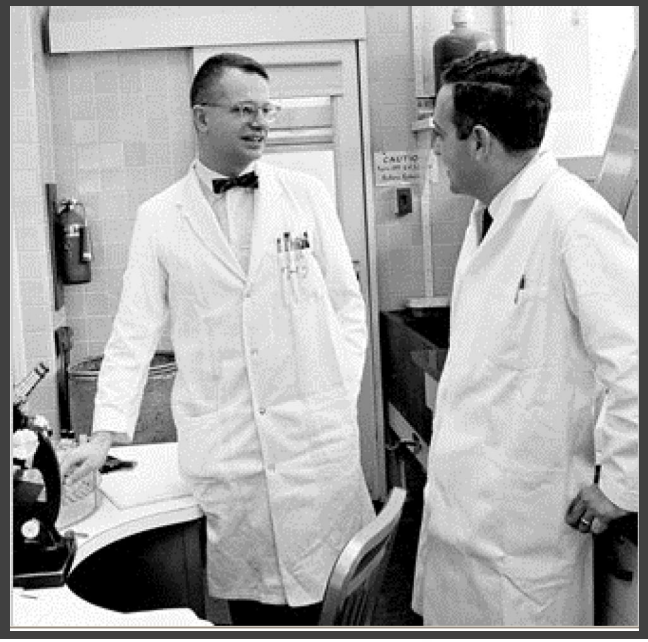
Australian Government
National Health and Medical Research Council
NHMRC

Summary:

Mild or Severe, Young or Old
Predictable or Unpredictable
Self limiting or Treatable
Inevitable or Preventable



The virus



RECOVERY FROM INFANTS WITH RESPIRATORY ILLNESS OF A VIRUS RELATED TO CHIMPANZEE CORYZA AGENT (CCA)

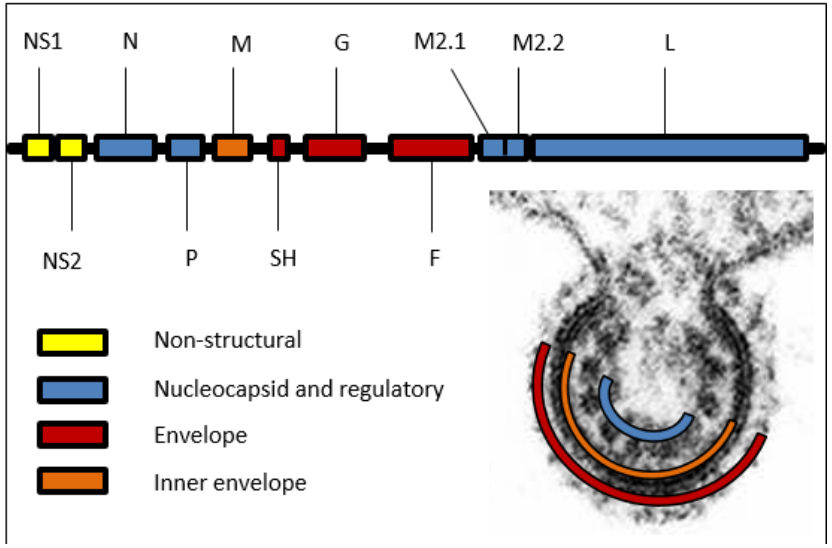
II. EPIDEMIOLOGIC ASPECTS OF INFECTION IN INFANTS AND YOUNG CHILDREN [1]

By

ROBERT CHANOCK [2] AND LAURENCE FINBERG [3]

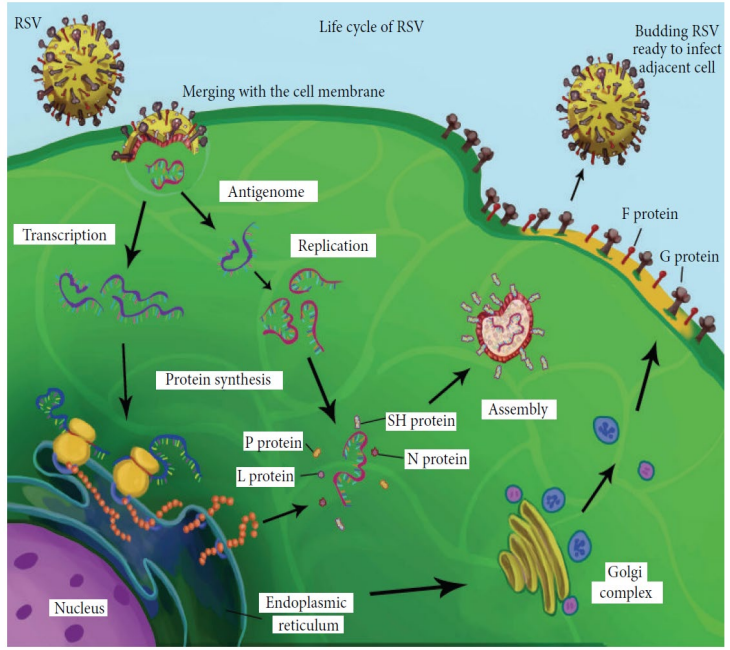
(*Received for publication July 22, 1957*)

- Species: Paramyxovirus
- Genus: Pneumovirus
- Two strains: A and B
- Lipid envelope
- Non segmented, negative single stranded linear RNA genome
- G and F (fusion) glycoproteins are essential for virulence



The virus

- G protein = targets ciliated cells of the airways facilitating adherence
- F protein = initiates viral penetration and promotes cell to cell spread
- Both F & G are key in eliciting a neutralizing antibody response
- Humoral and cytotoxic T cell-mediated immunity is vital



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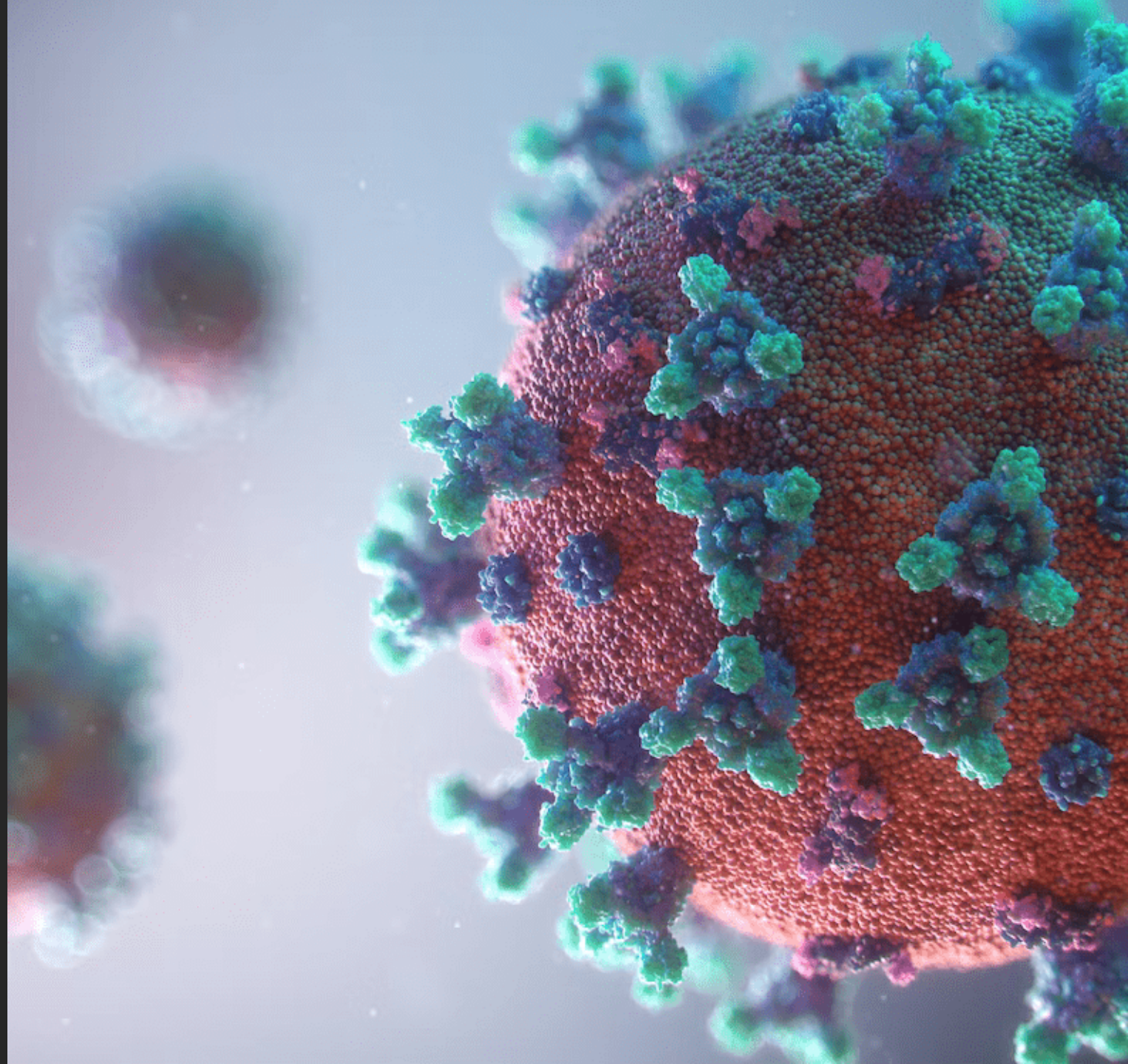
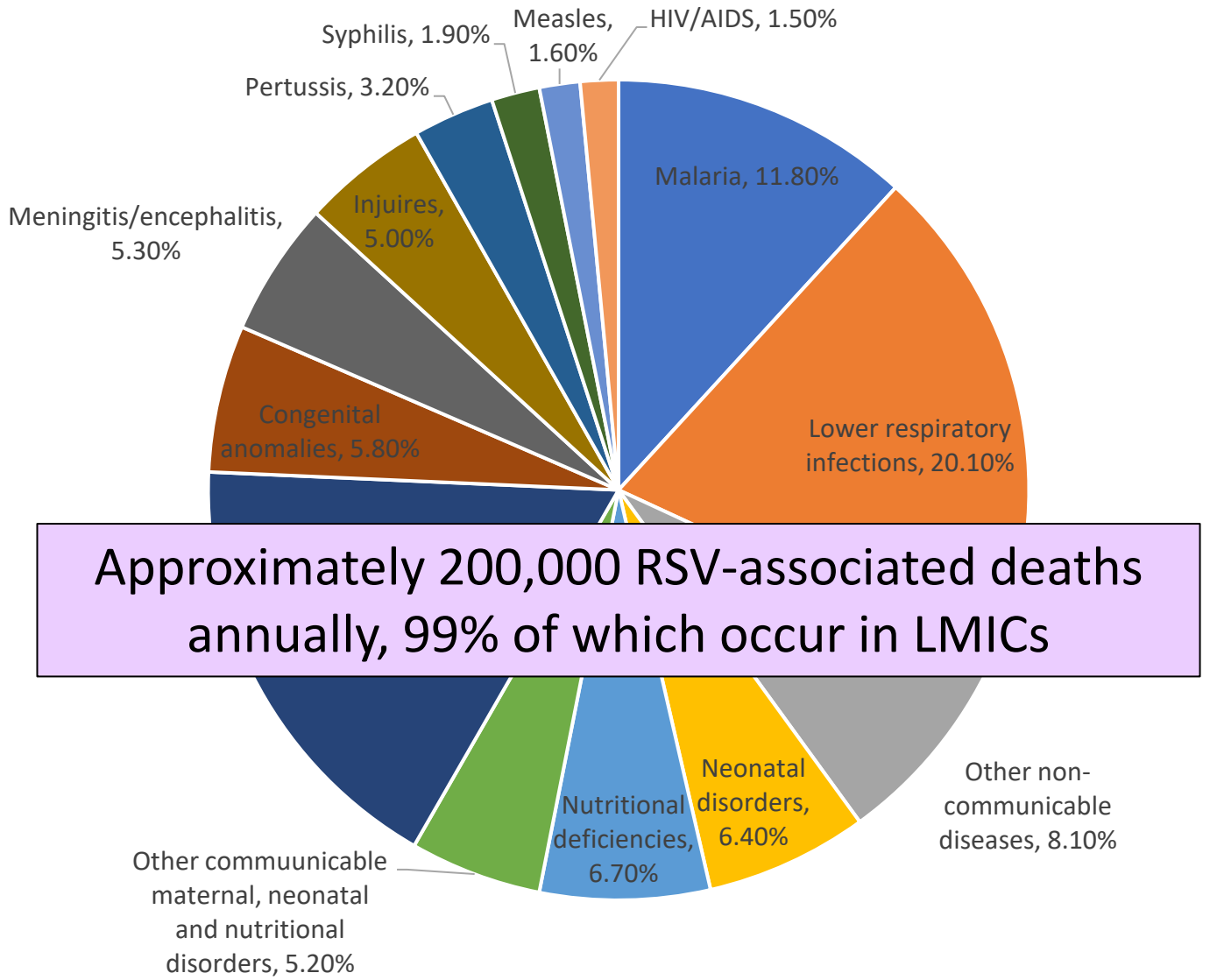


Mild or Severe, Young or Old



Lozano et al Lancet 2012

Mild or Severe, Young or Old

Prevalence of respiratory viruses in community-acquired pneumonia in children: a systematic review and meta-analysis

Mitchell T G Pratt, Tasnim Abdalla, Peter C Richmond, Hannah C Moore, Thomas L Snelling, Christopher C Blyth*, Mejbah U Bhuiyan*

Summary

Background Respiratory viruses are increasingly detected
prevalence estimates vary substantially. We aimed to systemat
associated with community-acquired pneumonia.

Methods We conducted a systematic review and meta-analy
respiratory viruses detected by any diagnostic method in c
pneumonia. We searched MEDLINE, PubMed, Embase, W
restrictions for relevant published articles and reports publis
review to pre-COVID-19 pandemic years. Three independer
predefined protocol. We calculated the pooled prevalence for
Laird random-effects models. We assessed bias using the Ne
in PROSPERO (CRD42016034047).

Findings We identified 186 eligible articles that represente
acquired pneumonia. One or more respiratory viruses wer
patients with a diagnosis of community-acquired pneum
syncytial virus (22·7%, 20·9–24·5) and rhinovirus (22·1%,
paediatric pneumonia globally, with other viruses detected i
prevalence by the country's national income, under-5 mortal

Interpretation Respiratory viruses are frequently detected in
ages and geographical regions, with non-significant varia
strategies to limit antibiotic use in children with viral pneun
targeting common respiratory viruses are expected to have
pneumonia.

Funding None.

	Overall		
	Number of studies	Prevalence (%)	I^2 (%)
Respiratory syncytial virus	150	22·7%	98·1%
Human rhinovirus	83	22·1%	98·5%
Human bocavirus	45	8·6%	98·1%
Human adenovirus (non-typed)	110	7·3%	97·0%
Human metapneumovirus	95	6·5%	96·3%
Human parainfluenza virus	58	6·6%	94·0%
Human parainfluenza virus 1	44	2·1%	88·6%
Human parainfluenza virus 2	40	1·1%	86·6%
Human parainfluenza virus 3	52	4·4%	94·4%
Human parainfluenza virus 4	20	2·0%	81·3%
Influenza (non-typed)	48	6·5%	89·9%
Influenza virus (non-typed)	61	5·5%	90·1%
Influenza virus H1N1	27	4·6%	93·9%
Influenza virus H3N2	16	4·8%	91·9%
Influenza B virus	58	1·8%	87·7%
Influenza C virus*	4	0·4%	50·8%
Human coronaviruses (non-typed)	32	3·5%	89·5%
Human coronaviruses NL63	19	1·0%	58·7%
Human coronaviruses 229E	15	1·2%	81·2%
Human coronaviruses OC43	20	2·3%	89·0%
Human coronaviruses HKU1	12	1·5%	87·7%
Enterovirus	33	3·7%	88·5%

Pratt et al, Lancet Child Adoles Health 2022

Mild or Severe, Young or Old

Estimated to cause:

- >10,000 hospitalisations in Australian infants
- Major contribution to winter bed block
- One in 50 babies admitted to hospital in the first year of life

	General Population Term Children	High-risk Children
Rates of hospitalization	1-2.9%	5-10%
Hospitalization Mean LOS (days)	3.4	5-7
Require ICU care	3-9%	10-50%
ICU Mean LOS (days)	3.4	4.5-7.2
Require mechanical ventilation	1.5%	17-40%

Nair et al. *Lancet* 2010.; Saravanos Med J Aust2019; Boyce et al. *J Pediatr* 2000; Joffe et al. *Pediatrics* 1999; Shay et al. *JAMA* 1999; Griffin et al. *Arch Int Med* 2002; Bockova et al. *Pediatrics* 2002; Horn et al. *J Pediatr* 2003; Moler et al. *Crit Care Med* 1992;

Mild or Severe, Young or Old

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HEALTH NEWS

Surge in cases of RSV, a virus that can severely sicken infants, is filling hospital beds

Pediatric doctors in five states said their hospital bed capacity was strained due to a sudden influx of RSV patients.

THE AGE SUBSCRIBE

National Victoria Coronavirus pandemic

Respiratory virus sends more children to hospital than flu or COVID

Timna Jacks
July 26, 2022 – 11.54am

Save Share A A A

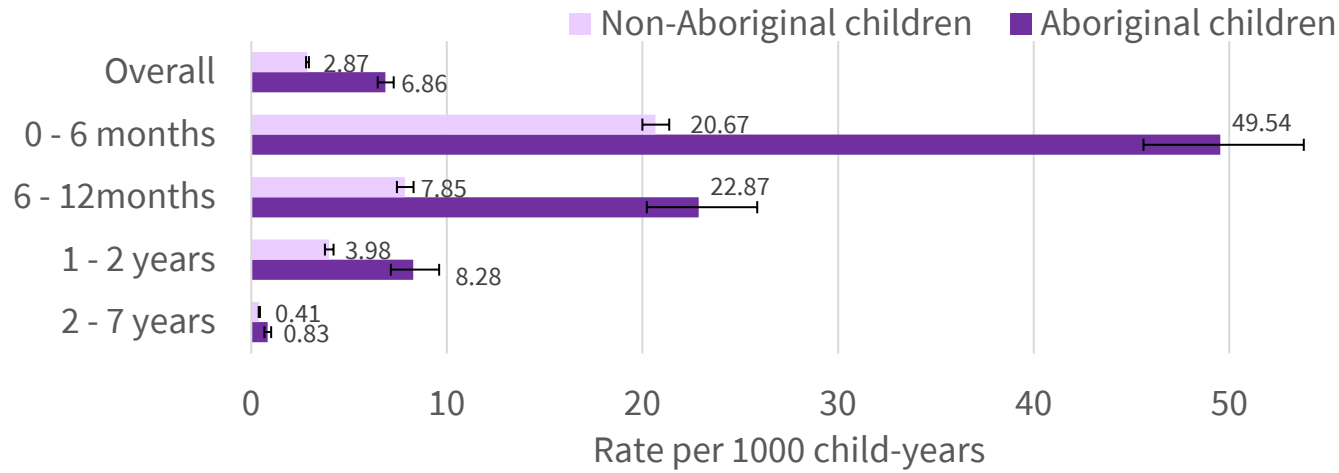
Doctors are warning of an outbreak of a potentially serious respiratory illness that can cause pneumonia among children, and is presently responsible for more paediatric admissions to Victorian hospitals than COVID-19 or the flu.

Children are presenting to hospitals with respiratory syncytial virus (RSV) at alarming rates this winter, after repeated lockdowns over the past two years contributed to waning immunity among children who were not exposed to an array of viruses, particularly those that cause flu-like symptoms.

prime video

Mild or Severe, Young or Old

The younger you are, the greater the risk



Children with underlying conditions at risk

- Prematurity
- Chronic cardio-respiratory conditions
- Chronic neurological conditions
- Genetic conditions including Trisomy 21

BUT: 83% of admissions are in previously healthy children

Sarna, Le, Moore et al; unpublished work

Mild or Severe, Young or Old

Symptoms develop **5 days** after exposure

Symptoms worsen over the first **3-4 days**

Symptoms can last **8-15 days**

Cough

Nasal Congestion/ secretions

Fever

Poor appetite

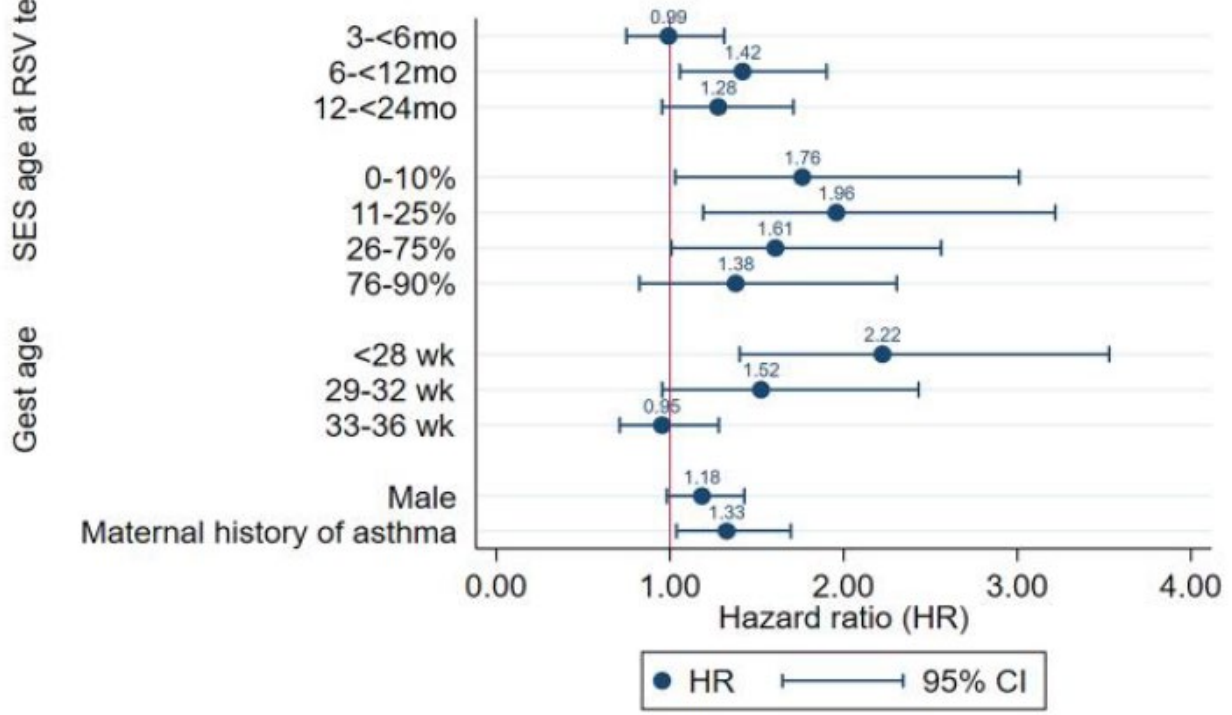
Wheeze/difficulty breathing

Sore Throat

Mild or Severe, Young or Old

RSV infection predisposes to longer term respiratory morbidity

Those born preterm and with a maternal history of asthma are at increased risk



Sarna M et al, Open Forum Inf Dis 2024

Mild or Severe, Young or Old

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 APRIL 28, 2005 VOL. 352 NO. 17

Respiratory Syncytial Virus Infection in Elderly and High-Risk Adults

Ann R. Falsey, M.D., Patricia A. Hennessey, R.N., Maria A. Formica, M.S., Christopher Cox, Ph.D., and Edward E. Walsh, M.D.

ABSTRACT

BACKGROUND

Respiratory syncytial virus (RSV) is an increasingly recognized cause of illness in adults. Data on the epidemiology and clinical effects in community-dwelling elderly persons

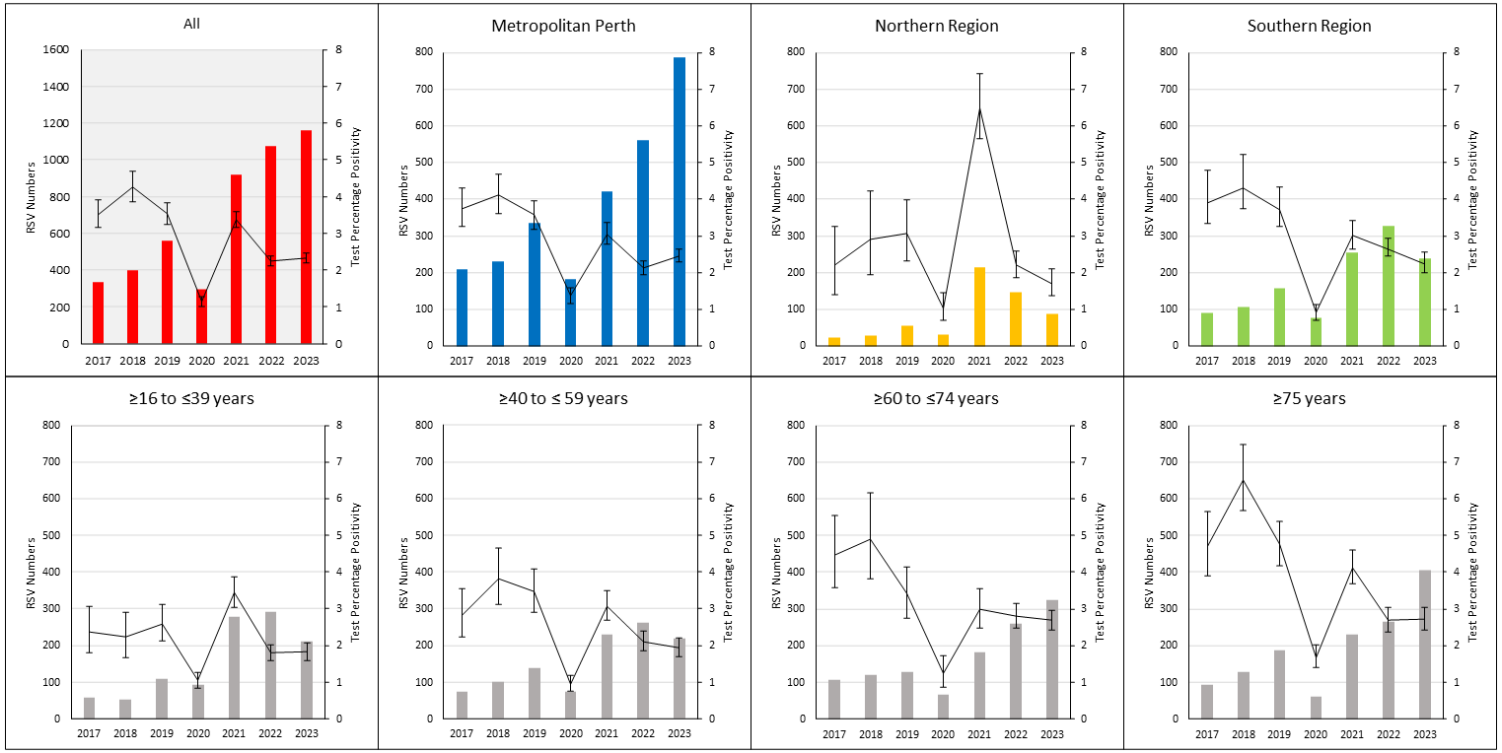
From the Department of Medicine, Rochester General Hospital (A.R.F., P.A.H.,

RSV infection occurs annually in:
i) 3-7% of heathy elderly
ii) 4-10% of high-risk adults
In hospitalised adults, RSV and influenza A resulted in similar LOS, ICU admission and mortality

cohorts and 142 hospitalized patients, and influenza A was diagnosed in 44 patients in the prospective cohorts and 154 hospitalized patients. RSV infection developed annual-

Falsey AR et al, NEJM 2005

Mild or Severe, Young or Old



The true burden of RSV disease in adults remains uncertain, because traditionally we have not tested for RSV.

Post COVID research is shedding new light on the burden in adults

Foley DA et al, Submitted manuscript

Mild or Severe, Young or Old

Contents lists available at ScienceDirect

Vaccine: X

journal homepage: www.elsevier.com/locate/jvacx

Influenza vaccination in Western Australian children: Exploring the health benefits and cost savings of increased vaccine coverage in children

Christopher C. Blyth [a,b,c,d,*], Parveen Fathima [a,e], Rebecca Pavlos [a], Peter Jacoby [f], Olivia Pavy [a], Elizabeth Geelhoed [f], Peter C Richmond [a,b,g,h], Paul V. Effler [i], Hannah C. Moore [a,j,*]

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[b] School of Medicine, University of Western Australia, Perth, WA, Australia
[c] Department of Infectious Diseases, Perth Children's Hospital, Perth, WA, Australia
[d] Department of Microbiology, PathWest Laboratory Medicine, QEII Medical Centre, Perth, WA, Australia
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ARTICLE INFO

Keywords:
Influenza
Influenza vaccination
Costs
Child

ABSTRACT

Introduction: To assess potential benefits and direct healthcare cost savings with expansion of an existing childhood influenza immunisation program, we developed a dynamic transmission model for the state of Western Australia, evaluating increasing coverage in children < 5 years and routinely immunising school-aged children.
Methods: A deterministic compartmental Susceptible-Exposed-Infectious-Recovered age-stratified transmission model was developed and calibrated using laboratory-notification and hospitalisation data. Base case vaccine coverage estimates were derived from 2019 data and tested under moderate, low and high vaccine effectiveness settings. The impact of increased coverage on the burden of influenza, influenza-associated presentations and net costs were assessed using the transmission model and estimated health utilisation costs.
Results: Under base case vaccine coverage and moderate vaccine effectiveness settings, 225,460 influenza cases are expected annually across all ages. Direct healthcare costs of influenza were estimated to be A$27,608,286 per annum, dominated by hospital costs. Net cost savings of >$A1.5 million dollars were observed for every 10 % increase in vaccine coverage in children < 5 years. Additional benefits were observed by including primary school age children (5–11 years) in the funded influenza vaccination program - a reduction in cases, presentations, hospitalisations and approximately $A4 million net costs savings were observed for every 10 % increase in coverage. The further addition of older children (12–17 years) resulted in only moderate additional net cost savings figures, compared with a 5–11year-old program alone. Net costs savings were predominantly derived by a reduction in influenza-associated hospitalisation in adults.
Conclusions: Any increase in influenza vaccine coverage in children < 5 years, above a base case of 50 % coverage resulted in a substantive reduction in influenza cases, presentations, hospitalisations and net costs when applied to the West Australian population. However, the most impactful pediatric program, from both a disease prevention and costs perspective, would be one that increased vaccination coverage among primary-school aged children.

Blyth et al, Vaccine X 2023

Summary:

Mild or Severe, Young or Old

Seasonal or Unpredictable

Self limiting or Treatable

Inevitable or Preventable

- RSV is one of the most common viral pathogens causing upper and lower respiratory infection.
- RSV occurs in all ages, in all countries with the burden of disease ranging for mild to severe.
- Unlike flu and COVID-19, we have limited understanding of who transmits to whom.
- A moderately effective treatment and prevention strategy, targeting those at risk of severe disease is likely to have a major impact

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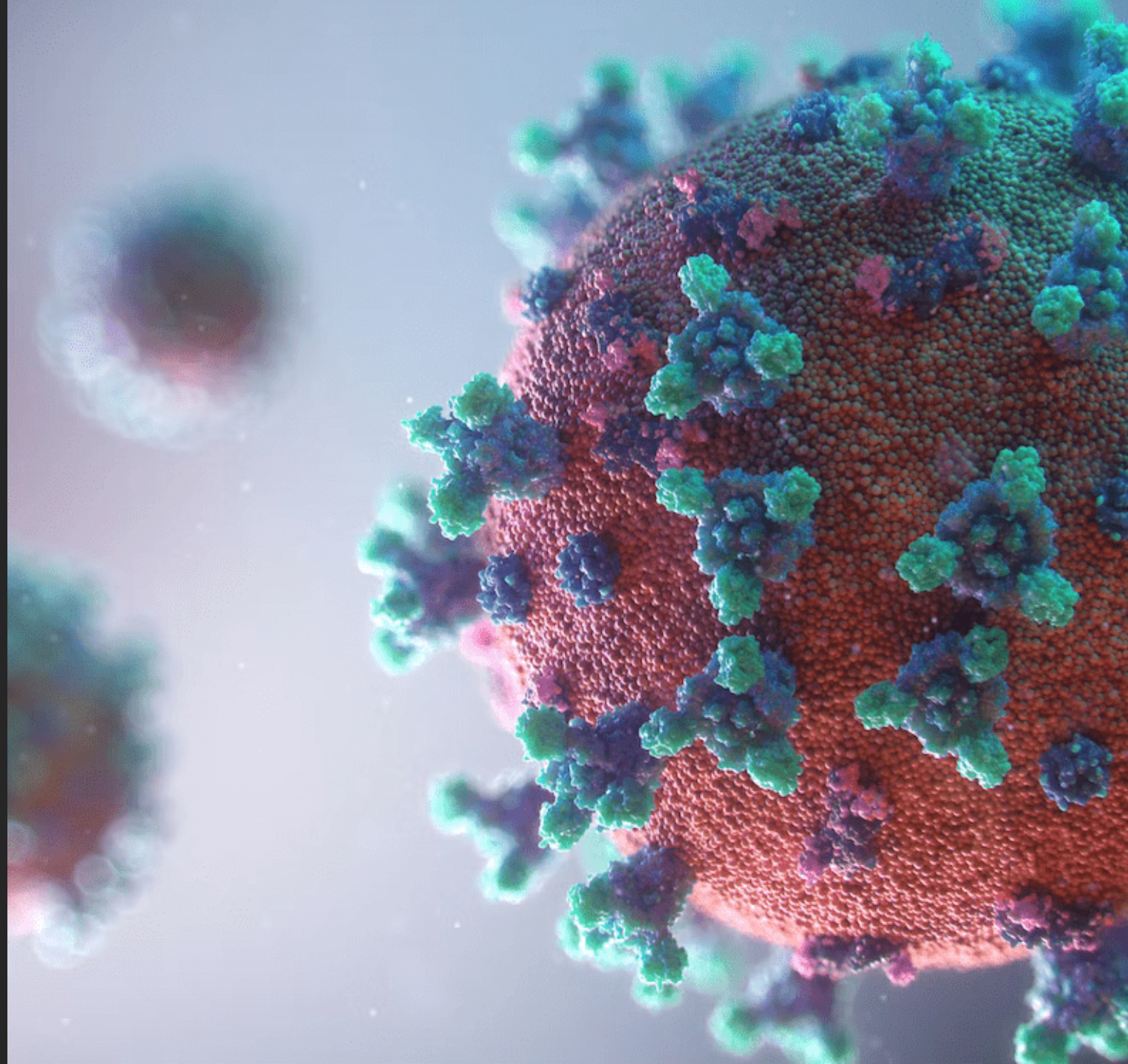


Predictable or Unpredictable

Every disease occurs at any season of the year but some of them more frequently occur and are of greater severity at certain times

Hippocrates, Book III of the Aphorisms

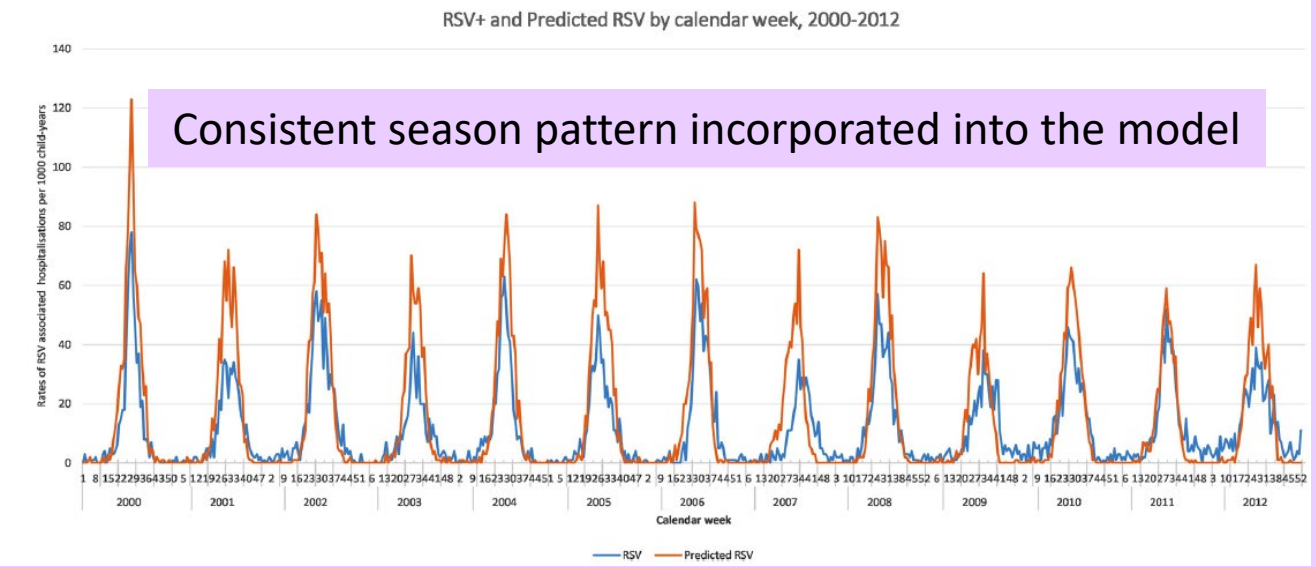
Predictable or Unpredictable

scientific reports

Check for updates

OPEN

Developing a prediction model to estimate the true burden of respiratory syncytial virus (RSV) in hospitalised children in Western Australia

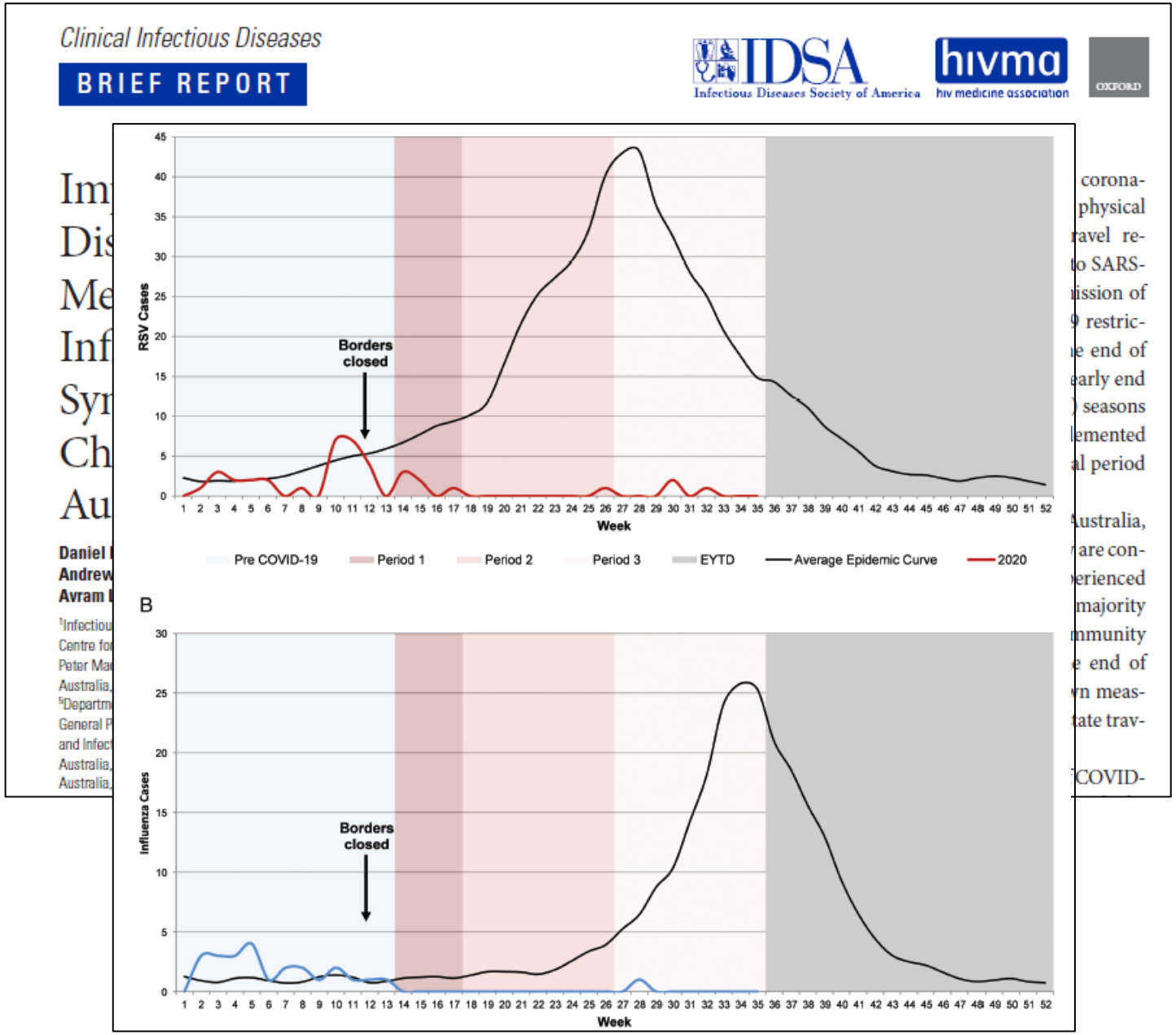


Consistent season pattern incorporated into the model

causing 3.2 million detected hospitalisation episodes every year[1]. The true burden is likely to be much greater, with approximately half of RSV-associated deaths estimated to occur outside of hospital[1]. In Australia, for every

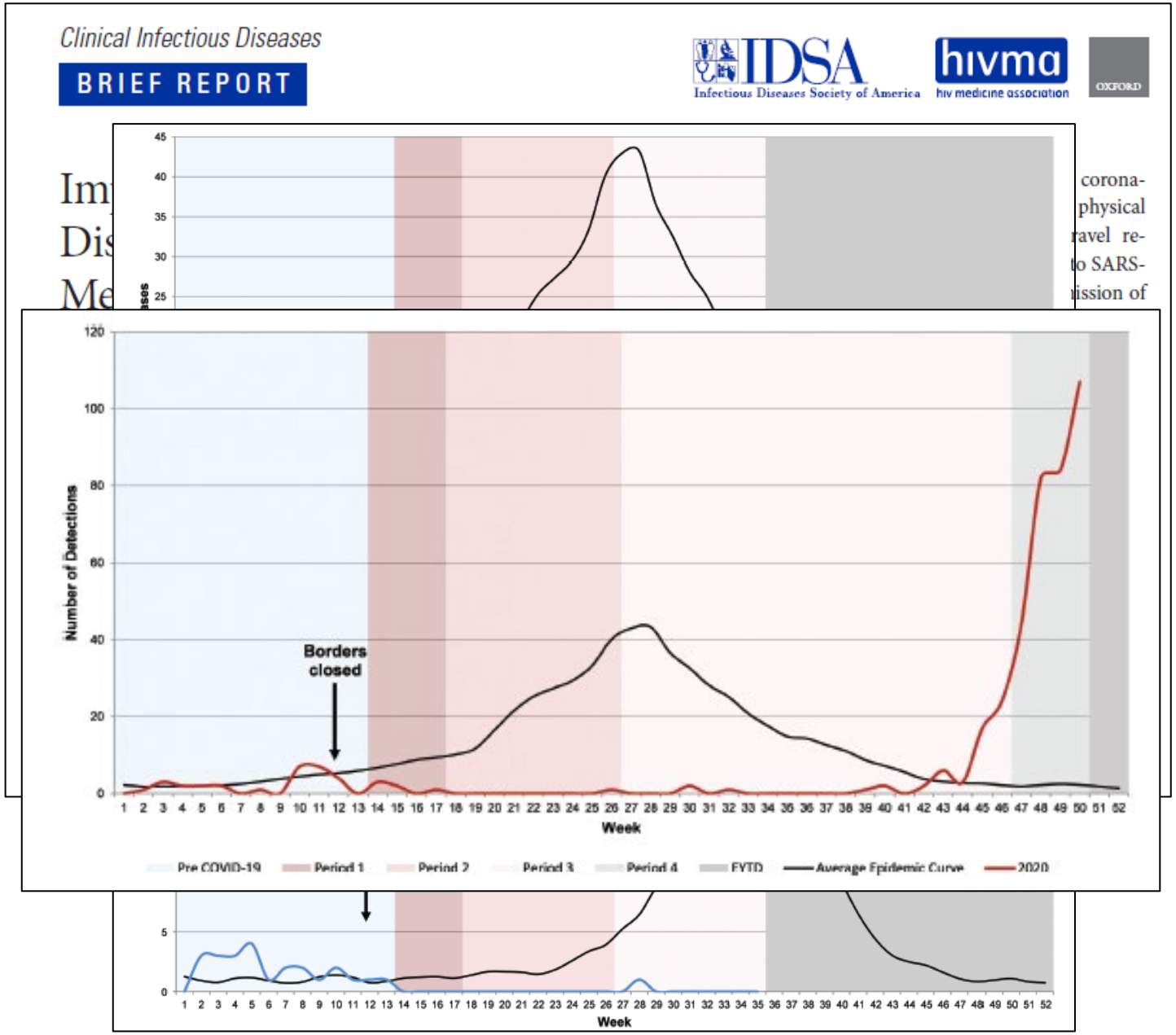
Gebremedhin AT et al, Nature Sci Rep 2022

Predictable or Unpredictable



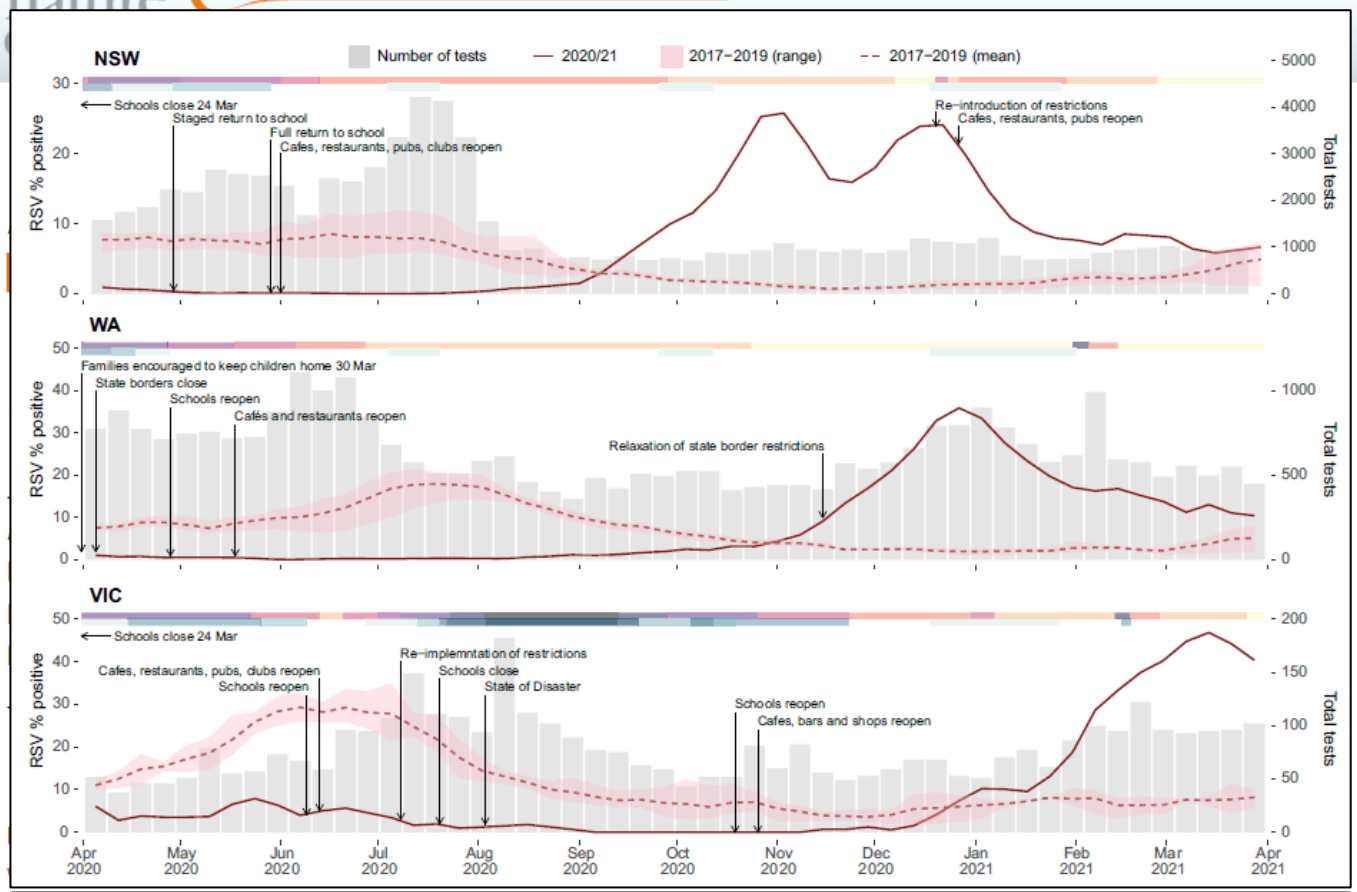
Yeoh et al, CID 2021

Predictable or Unpredictable



Yeoh DK et al, CID 2021; Foley DA et al, CID 2021

Predictable or Unpredictable

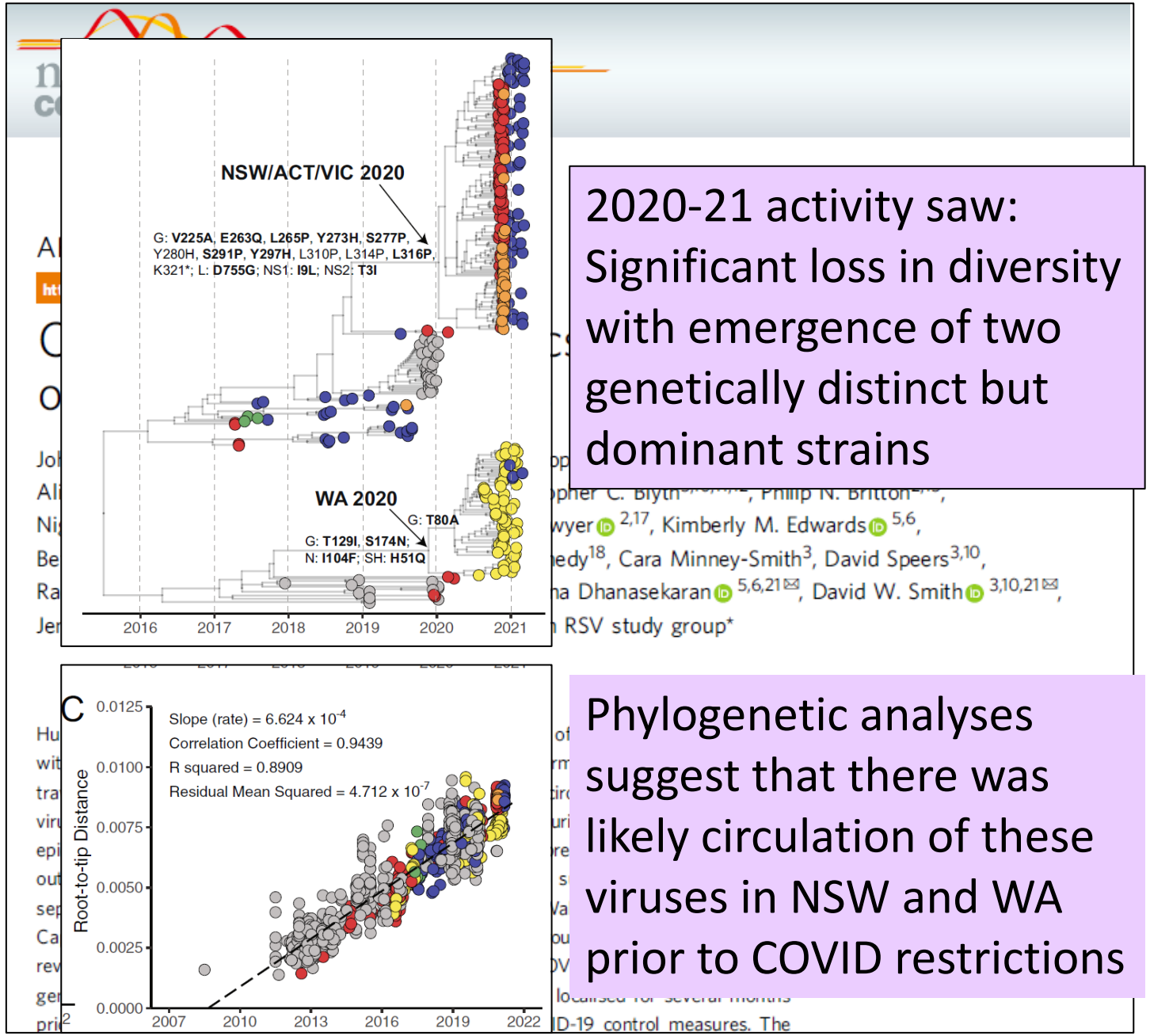


Out of season RSV epidemics occurred in all Australia states, but at different times:
NSW to WA to Victoria

genetically distinct RSV-A clades circulating cryptically, likely localised for several months prior to an epidemic surge in cases upon relaxation of COVID-19 control measures. The

Eden JS et al, Nat Comm 2022

Predictable or Unpredictable



2020-21 activity saw: Significant loss in diversity with emergence of two genetically distinct but dominant strains

Phylogenetic analyses suggest that there was likely circulation of these viruses in NSW and WA prior to COVID restrictions

Eden JS et al, Nat Comm 2022

Summary:

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- During COVID-19, the predictable pattern of RSV became unpredictable
- COVID-19, the disrupter, forced us to question many of the assumptions that we previously made about seasonality and transmission
- BUT, RSV has returned to a normal seasonal pattern with activity expected to commence in April-May 2024

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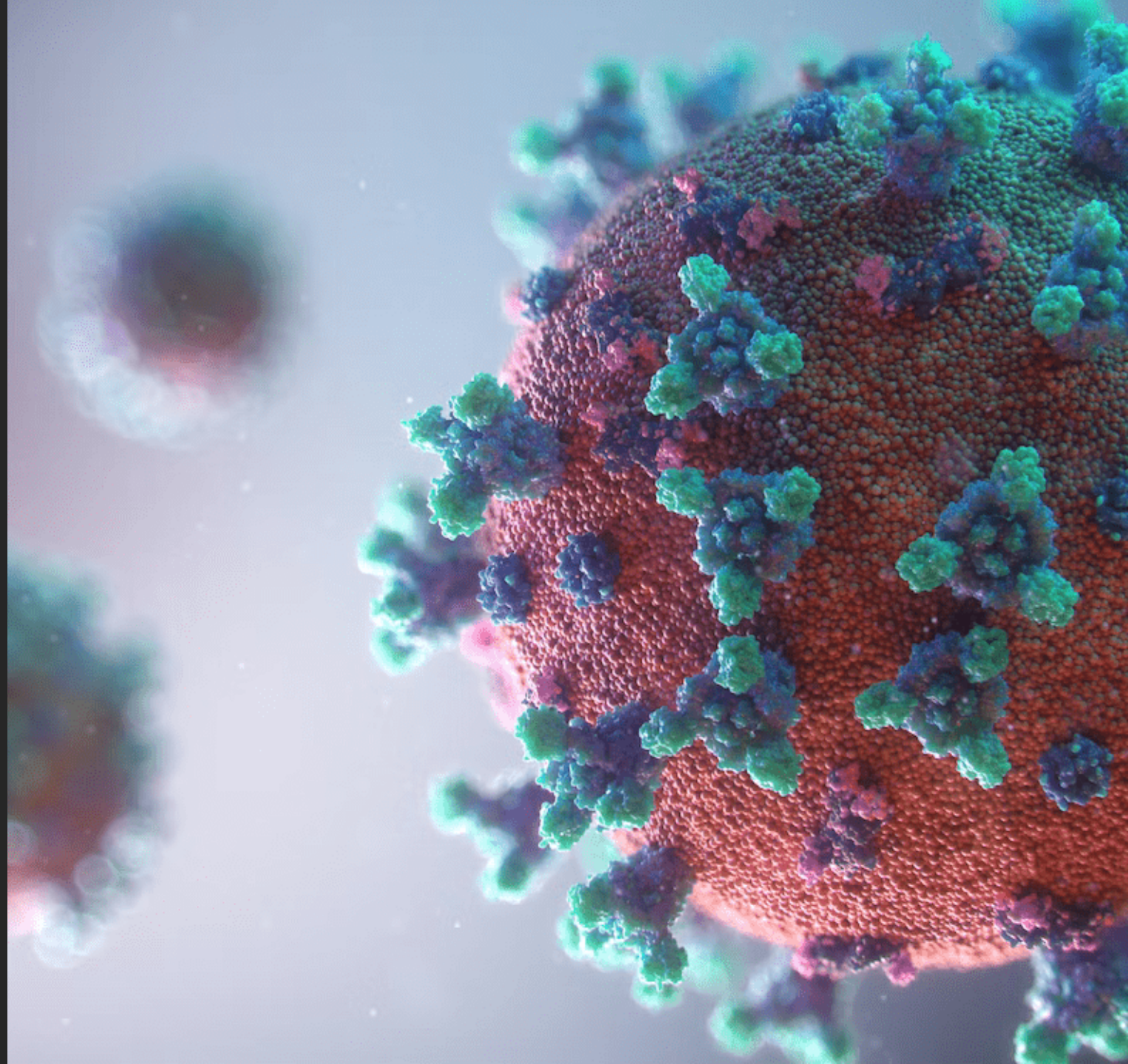
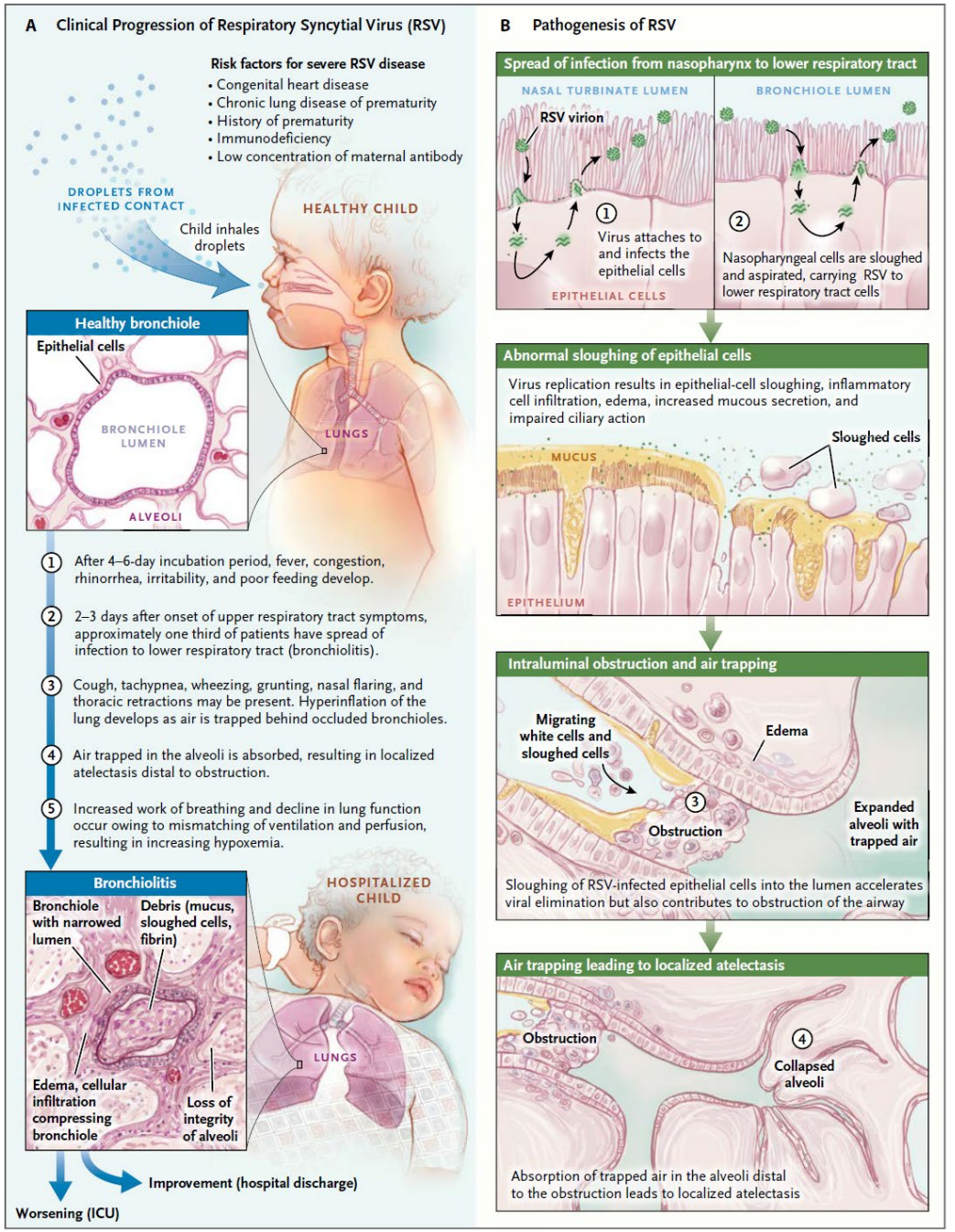


Self limiting or Treatable



Cody Meissner H et al. NEJM 2016

Self limiting or Treatable

Cochrane Library
Trusted evidence.
Informed decisions.
Better health.

Cochrane Database of Systematic Reviews

[Intervention Review]

Ribavirin for respiratory syncytial virus infection of the lower respiratory tract in infants and young children

Kathleen Ventre[1], Adrienne Randolph[2]

[1]Division of Critical Care Medicine, Primary Children's Medical Center, Salt Lake City, Utah, USA. [2]MICU Children's Hospital, Farley 517, Boston, Massachusetts, USA

Contact address: Kathleen Ventre, Division of Critical Care Medicine, Primary Children's Medical Center, 100 N. Medical Drive, Salt Lake City, Utah, 84113, USA. kathleen.ventre@hsc.utah.edu.

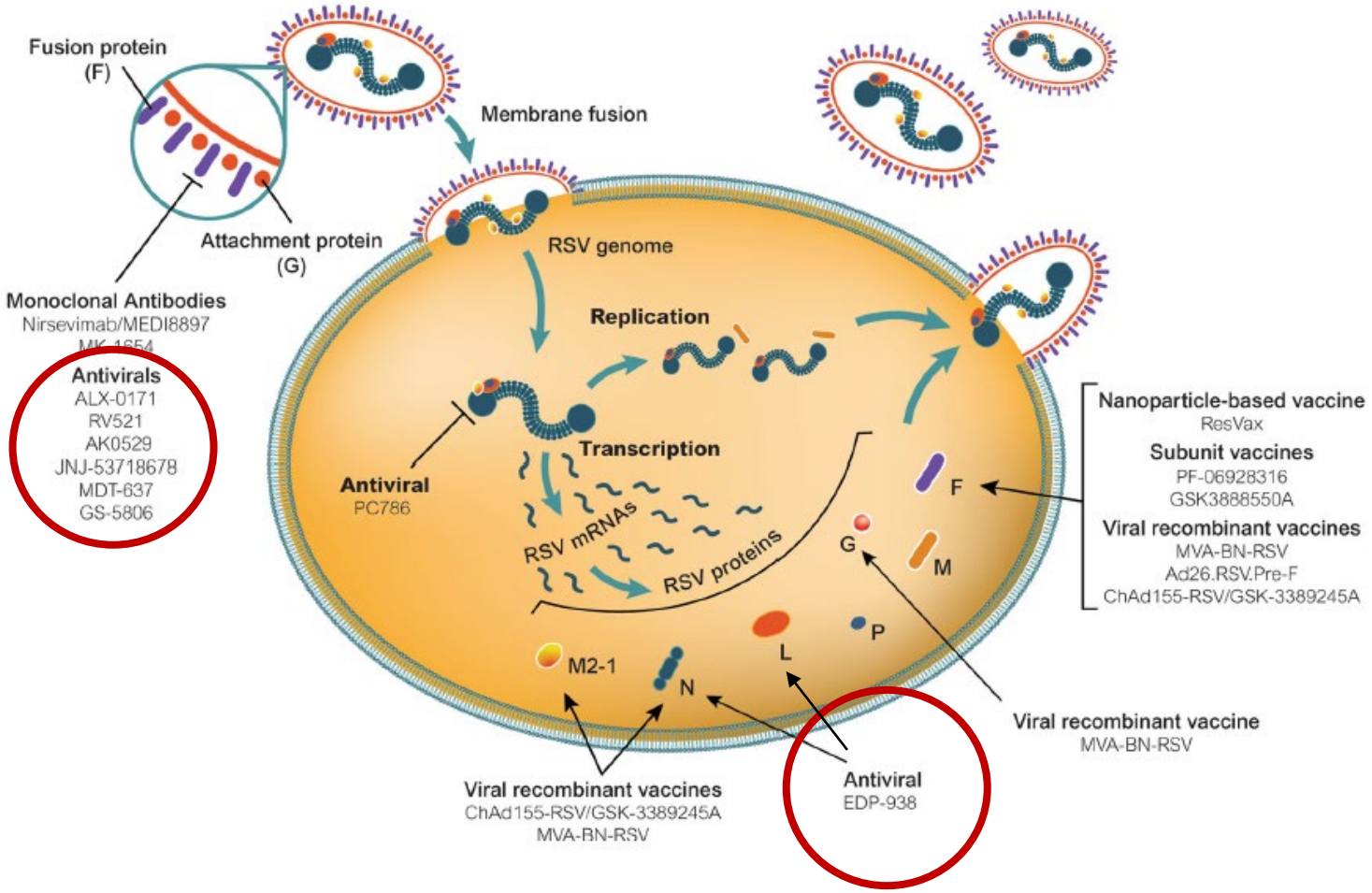
Editorial group: Cochrane Acute Respiratory Infections Group.
Publication status and date: Withdrawn from publication for reasons stated in the review, published in Issue 5, 2010.

Citation: Ventre K, Randolph A. Ribavirin for respiratory syncytial virus infection of the lower respiratory tract in infants and young children. Cochrane Database of Systematic Reviews 2010, Issue 5. Art. No.: CD000181. DOI: 10.1002/14651858.CD000181.pub4

12 trials included:
Mortality – OR: 0.58 (0.18, 1.85)
Respiratory Deterioration – OR: 0.37 (0.12, 1.18)
Days of ventilation - 1.9 fewer days (-4.6 to +0.9)

Centre K et al, Cochrane 2010

Self limiting or Treatable



Domachowske JB et al, Infect Dis Ther 2021

Self limiting or Treatable

Journal of Medicinal

12th International RSV Symposium in Belfast (September 2022)

Phase III double blind randomised control trial

Children 1-23 months with RSV-bronchiolitis

AK0529 twice daily for 5d / placebo

Primary outcome: Change in bronchiolitis score

Secondary outcomes: incl virological outcomes

ArkBio

30% reduction in bronchiolitis score (p=0.002)
77% reduction in viral load (p=0.006)

- Phase 3 AirFLO study with ziresovir met primary and key secondary endpoints of significant reduction of sign-and-symptom score (p=0.002) and viral load (p=0.006) respectively, compared with placebo
- Respiratory syncytial virus (RSV) infection is a leading cause of hospitalization and death in children under five years old
- Ziresovir is the first antiviral drug successfully completing a pivotal phase 3 study in this patient population
- Regulatory submission in China planned for Mid-2022

clinical isolates of RSV in cellular assays, and more than one log viral load reduction in BALB/c mouse model of RSV viral infection. RO-0529 was proven to be a specific RSV F protein inhibitor by identification of drug resistant mutations of D486N, D489V, and D489Y in RSV F protein and the inhibition of RSV F protein-induced cell−cell fusion in cellular assays.

Zheng X et al. J Med Chem 2019

Summary:

Mild or Severe, Young or Old
Seasonal or Unpredictable
Self limiting or Treatable
Inevitable or Preventable

- RSV is self-limiting in most children and adults – supportive care is required
- If demonstrated to be effective, antivirals are likely play a role in high-risk populations or those with severe disease
- Evolution of drug targets will remain a future challenge
- Targeted immunomodulation may provide new therapeutic avenues

Summary:

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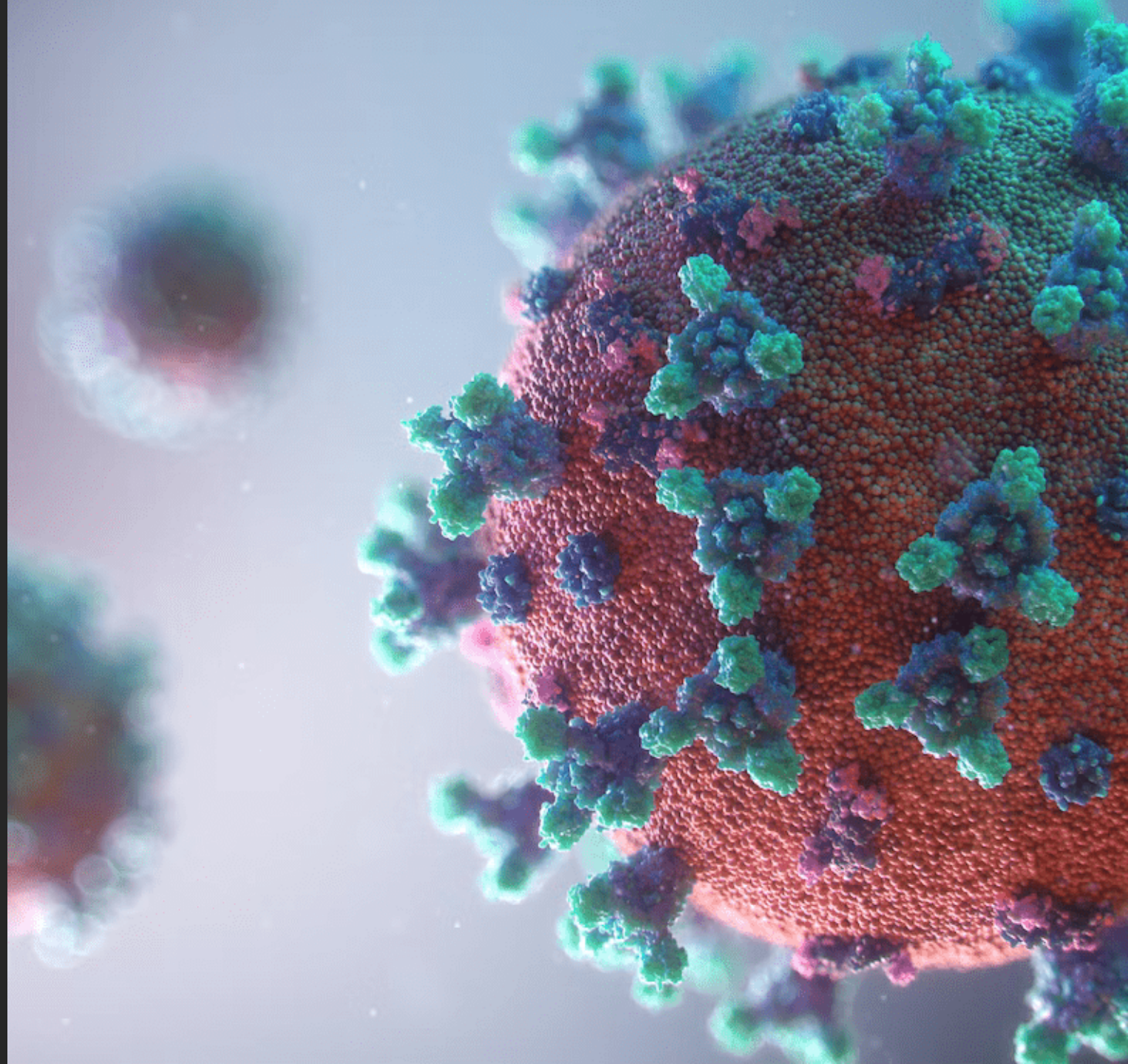
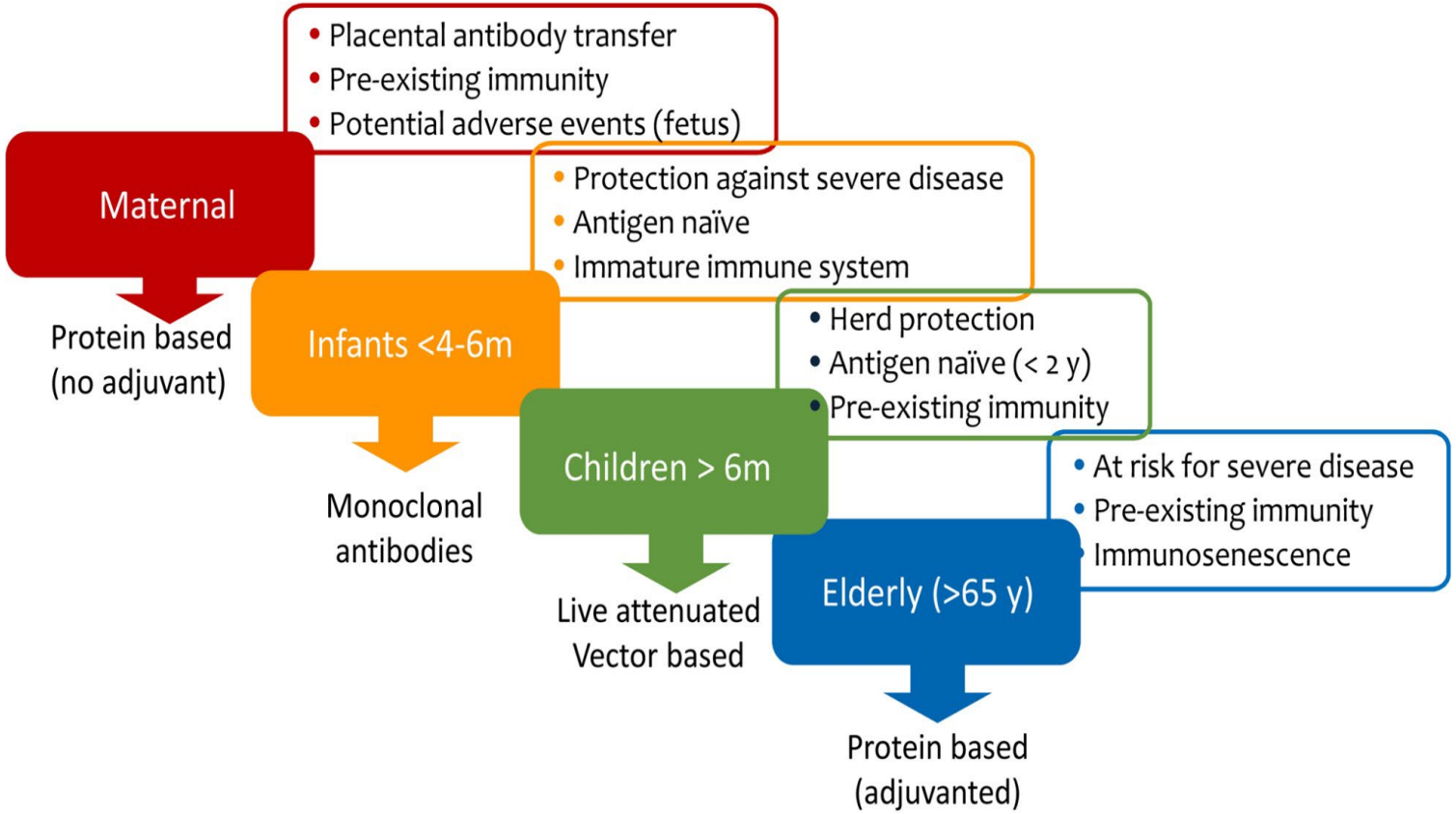


Inevitable or Preventable



Inevitable or Preventable

The NEW ENGLAND JOURNAL of MEDICINE

RSV fusion (F) protein nanoparticle vaccine, administered between 28 and 36 weeks gestation

RCT: RSV-associated medically significant LRTI up to 90 days of life

RSV+ve by PCR; one LRTI manifestation; evidence of medical significance (hypoxic or tachpneic)

(87 countries; mostly South Africa and USA)

	Vaccine	Placebo	% reduction
RSV-associated medically significant LRTI	41/2765 (1.5%)	35/1430 (2.4%)	39.4% (-1.0, 63.7%)
RSV hospitalisation	57/2765 (2.1%)	53/1430 (3.7%)	44.4% (19.6, 61.5)
RSV LRTI with severe hypoxaemia	14/2765 (0.51%)	14/1430 (0.98%)	48.3% (-8.2; 75.3)

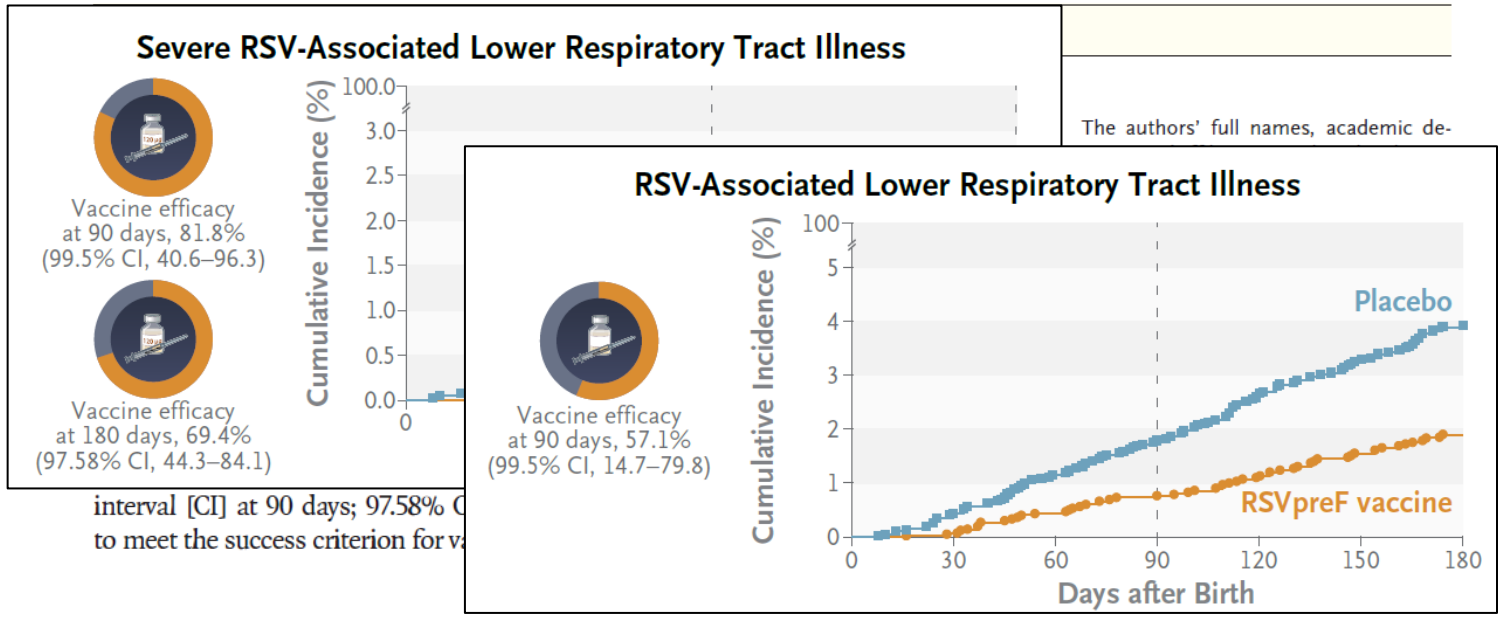
cess, lower bound of the 97.52% confidence interval [CI] of ≥30%).

RESULTS

Madhi SA et al, NEJM 2020

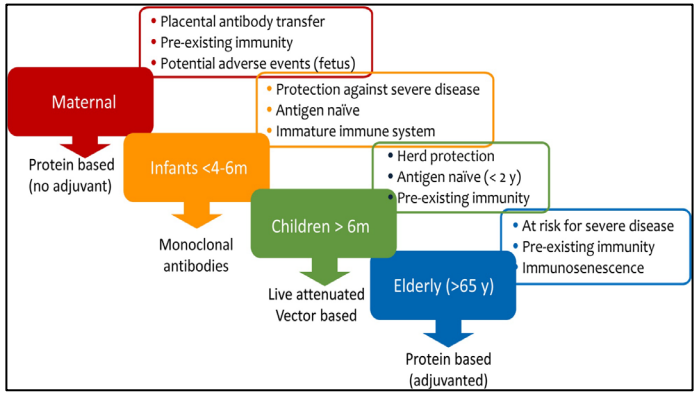
Inevitable or Preventable

Bivalent prefusion F protein based RSV vaccine, administered between 24 and 36 weeks gestation
RCT: RSV-associated medically significant LRTI and severe LRTI at 90-180 days of life
RSV+ve by PCR; severe defined as fast breathing; hypoxia, respiratory support of ICU admission
(18 countries; USA; South Africa; Argentina; Japan)

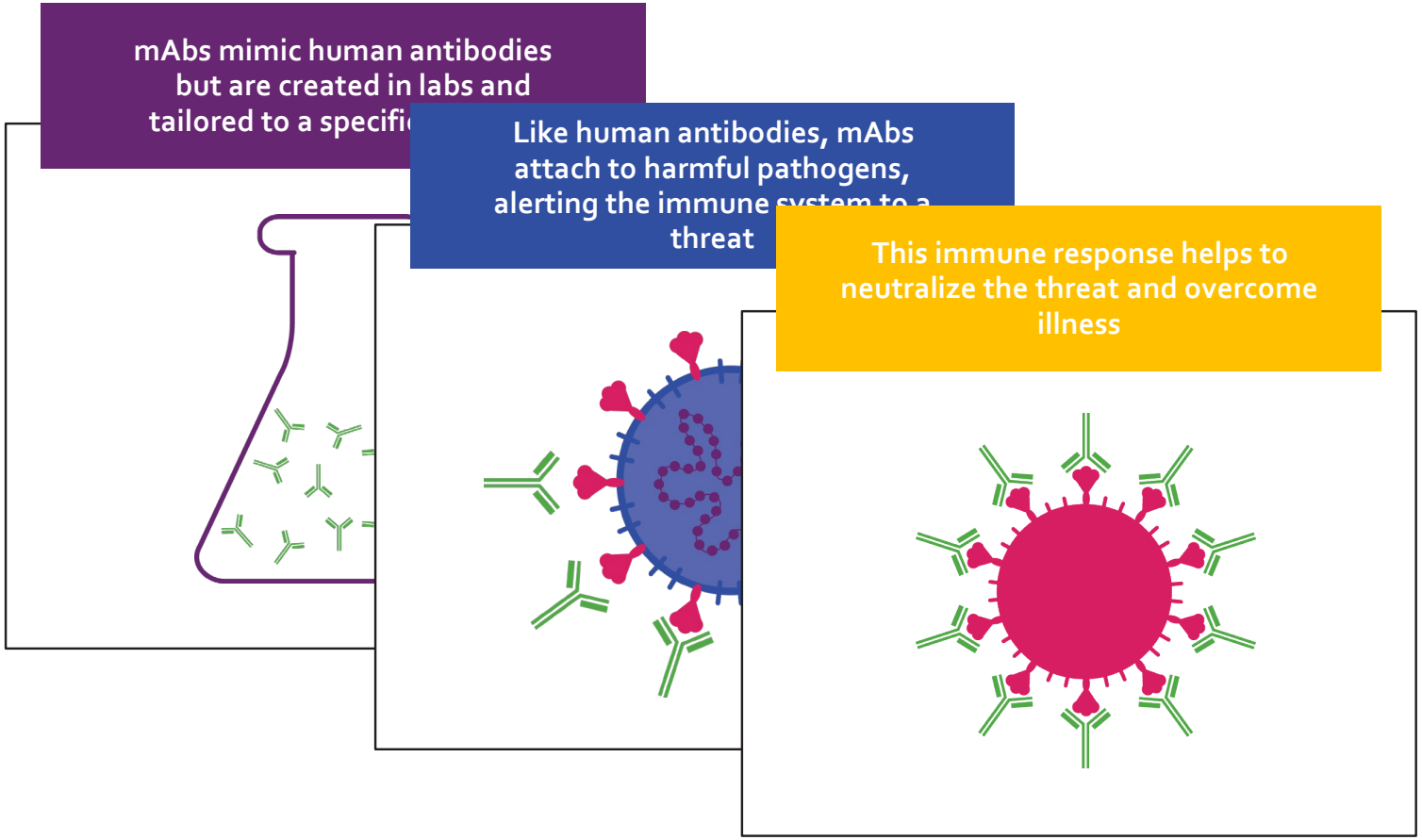


Kampmann B et al, NEJM 2023

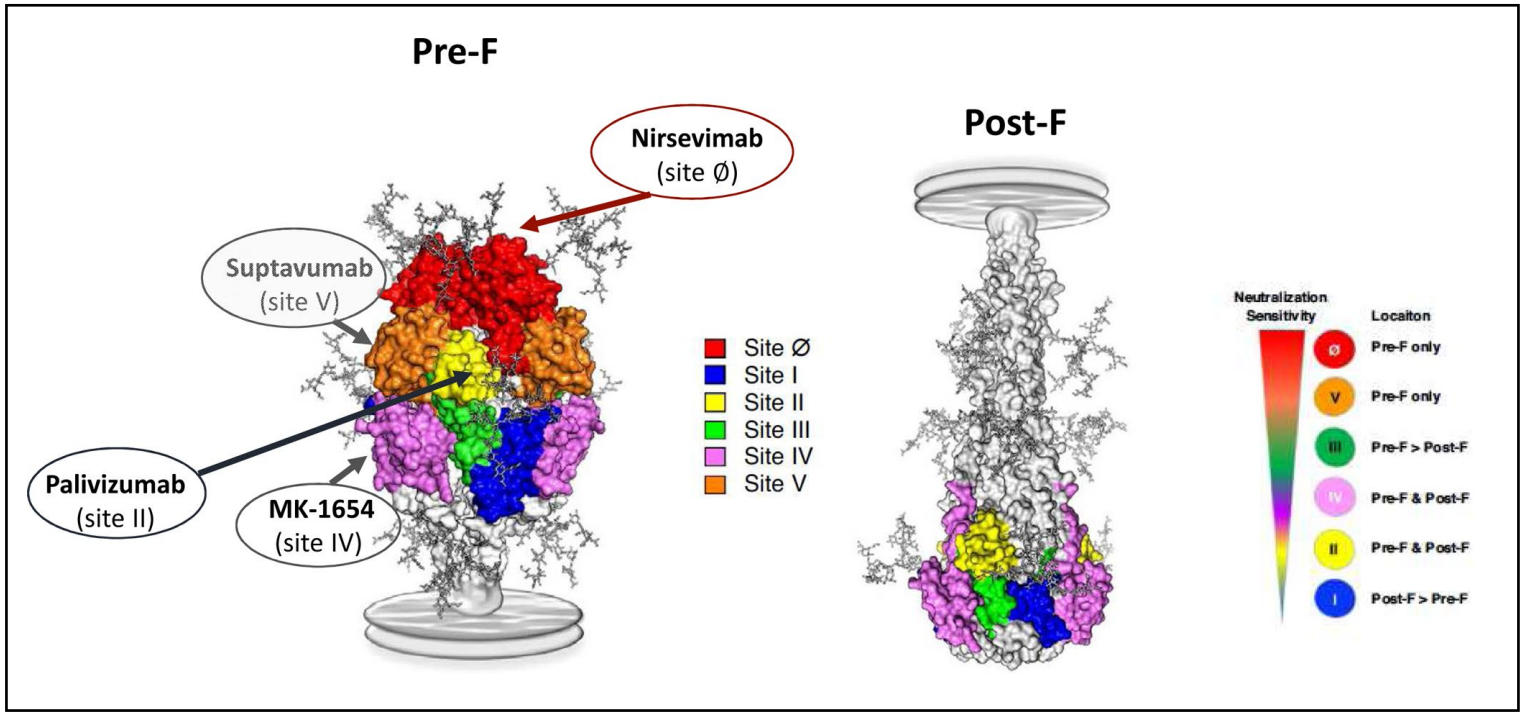
Inevitable or Preventable



What are monoclonal antibodies?



Inevitable or Preventable



Success of monoclonal antibodies for RSV prevention has been demonstrated:

- Palivizumab
- Suptavumab
- Nirsevimab

Inevitable or Preventable

Humanised murine monoclonal antibody directed against single epitope on the fusion glycoprotein
RCT and post-implementation effectiveness has been demonstrated
Monthly IM injection and high cost limit utility

	Placebo	Palivizumab	% reduction
Primary analysis (premature or those with BPD)			
Incidence of RSV hospitalisation	53/500 (10.6%)	48/1002 (4.8%)	55% (38,72)
Subgroup analysis			
Premature (<35weeks; no BPD)	19/234 (8.1%)	9/506 (1.8%)	78% (66,90)
BPD	34/266 (12.8%)	39/496 (7.9%)	39% (20,58)

Antibody, Reduces Hospitalization From Respiratory Syncytial Virus

mechanical ventilation. The incidence of hospitalization for respiratory illness not caused by RSV and the incidence of otitis media were also evaluated. The placebo

serious RSV illness in premature children and those with BPD. *Pediatrics* 1998;102:531–537; *respiratory syncytial virus, monoclonal antibody, prophylaxis, MEDI-493, palivizumab, Synagis, prematurity, bronchopulmonary*

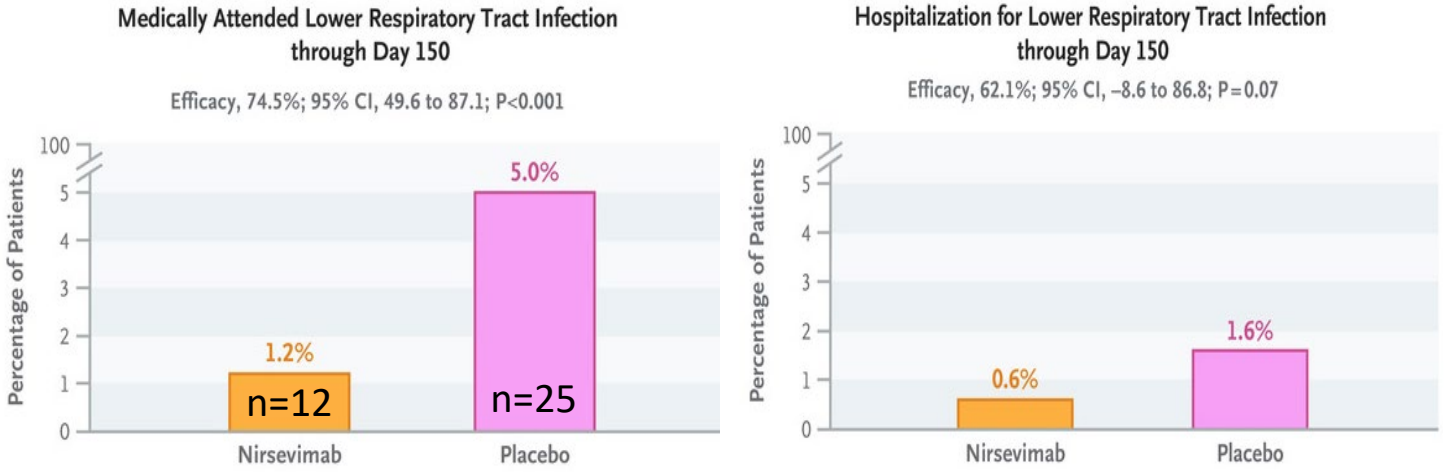
Impact-RSV Study Group, Pediatrics 1998

Inevitable or Preventable

The NEW ENGLAND JOURNAL of MEDICINE

A long-acting monoclonal directed against the prefusion F protein binding epitope
RCT: Medically attended RSV-associated LRTI out to 150 days in healthy term and late preterm infants (20 countries)

A single dose resulted in significant reduction in medically attended RSV-associated LRTI



A total of 1490 infants underwent randomization: 994 were assigned to the nirsevimab group and 496 to the placebo group. Medically attended RSV-associated lower respiratory tract infection occurred in 12 infants (1.2%) in the nirsevimab

...nesburg (S.A.M.), and the Department of Paediatrics and Child Health, Red Cross Children's Hospital, and the Medical Research Council Unit on Child and Adoles-

Hammitt LL et al, NEJM 2022

Inevitable or Preventable

▼This medicinal product is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems.

AUSTRALIAN PRODUCT INFORMATION BEYFORTUS™ (NIRSEVIMAB) SOLUTION FOR INJECTION

1 NAME OF THE MEDICINE

Nirsevimab

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

BEYFORTUS 50 mg solution for injection in prefilled syringe

Each pre-filled syringe contains 50 mg of nirsevimab in 0.5 mL (100 mg/mL).

BEYFORTUS 100 mg solution for injection in prefilled syringe

Each pre-filled syringe contains 100 mg of nirsevimab in 1 mL (100 mg/mL).

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Solution for injection

Clear to opalescent, colourless to yellow, pH 6.0 solution in a prefilled syringe

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

BEYFORTUS is indicated for the prevention of Respiratory Syncytial Virus (RSV) lower respiratory tract disease in:

- 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.

BEYFORTUS should be used in accordance with official recommendations.

Beyfortus, TGA

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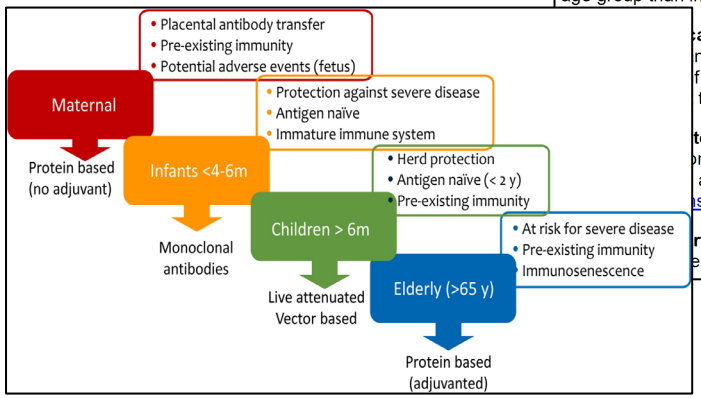

Australian Government
Department of Health and Aged Care

AUSTRALIAN TECHNICAL ADVISORY GROUP ON IMMUNISATION (ATAGI)
CLINICAL ADVICE

Version 1.0 Issue date: March 2024

STATEMENT ON THE CLINICAL USE OF AREXVY (RSV PRE-F3) VACCINE FOR PREVENTION OF RESPIRATORY SYNCYTIAL VIRUS (RSV) DISEASE IN OLDER ADULTS IN AUSTRALIA

A new chapter on RSV in the Australian Immunisation Handbook is being prepared and will be available at immunisationhandbook.health.gov.au by mid-2024. Until then, use this statement for clinical practice guidance.

RSV vaccine

One vaccine is currently available on the private market in Australia for adults aged ≥60 years to prevent illness and severe complications associated with RSV infection:

- **Arexvy** (GlaxoSmithKline) is an adjuvanted recombinant RSV vaccine. Arexvy is administered as a single dose of 0.5 mL by intramuscular injection and may be given at any time of the year. It is registered for use in adults ≥60 years of age. At this time, Arexvy is available only through private prescription. It is not currently funded under the National Immunisation Program (NIP).

ATAGI recommendations

A single dose of Arexvy RSV vaccine is recommended for the following groups:

- **All adults aged ≥75 years**, who have the highest burden of RSV hospitalisation and are likely to have the greatest benefit from vaccination.
- **Aboriginal and/or Torres Strait Islander peoples aged 60 to 74 years**, who have a rate of RSV-associated hospitalisation that is similar to non-Indigenous Australians aged ≥75 years.
- **Adults aged 60 to 74 years with medical conditions that increase their risk of severe disease due to RSV** (see Table 1).

All other adults aged 60 to 74 years can consider RSV vaccination. The burden of RSV disease is lower in this age group than in people aged ≥75 years, so the benefits of vaccination may be less.

an be co-administered with other vaccines for older adults, such as COVID-19, influenza, nd recombinant zoster (Shingrix) vaccines. There is an increased likelihood of local and systemic f Arexvy is co-administered with other vaccines, but the benefits of co-administration should be this.

ter Arexvy RSV vaccine to pregnant women or infants. If Arexvy is inadvertently administered oman or infant, monitor for adverse events following immunisation. No specific management is any adverse events to the Therapeutic Goods Administration (TGA) and/or state and territory s.

rther doses in the future has not yet been established. Recommendations on the need for es will be provided when evidence is available.

ATAGI statement: rexvy-rsv-pre-f3-vaccine-for-rsv.pdf

Summary:

Mild or Severe, Young or Old
Seasonal or Unpredictable
Self limiting or Treatable
Inevitable or Preventable

After years of disappointment, 2021-2024 has been an exciting period in the RSV world:

- Safe and effective long-acting monoclonals for infants
- Safe and effective maternal vaccines
- Safe and effective vaccines for adults

RSV is not inevitable – it is now preventable

Acknowledgements:

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