Government of **Western Australia**
Department of **Health**

RSV Infant Immunisation Program Information Session 2024

13 March 2024

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CDCD

Conflict of Interest Disclaimer

- No stock holdings
- No pharmaceutical affiliations
- No pharmaceutical payments

Outline

- RSV epidemiology in WA
- Nirsevimab
  - Effectiveness
  - Safety
- Anticipated benefits of universal immunisation of young infants

RSV Epidemiology

- RSV is the leading cause of infant hospitalisation in Australia.
- > 50% of all infants are infected in the first year of life.
- In WA, approximately 1 in every 25 infants are hospitalised with RSV in the first year of life.
- RSV infection early in life is associated with developing childhood asthma.

› Lancet. 2023 May 20;401(10389):1669-1680. doi: 10.1016/S0140-6736(23)00811-5.
Epub 2023 Apr 20.

Respiratory syncytial virus infection during infancy and asthma during childhood in the USA (INSPIRE): a population-based, prospective birth cohort study

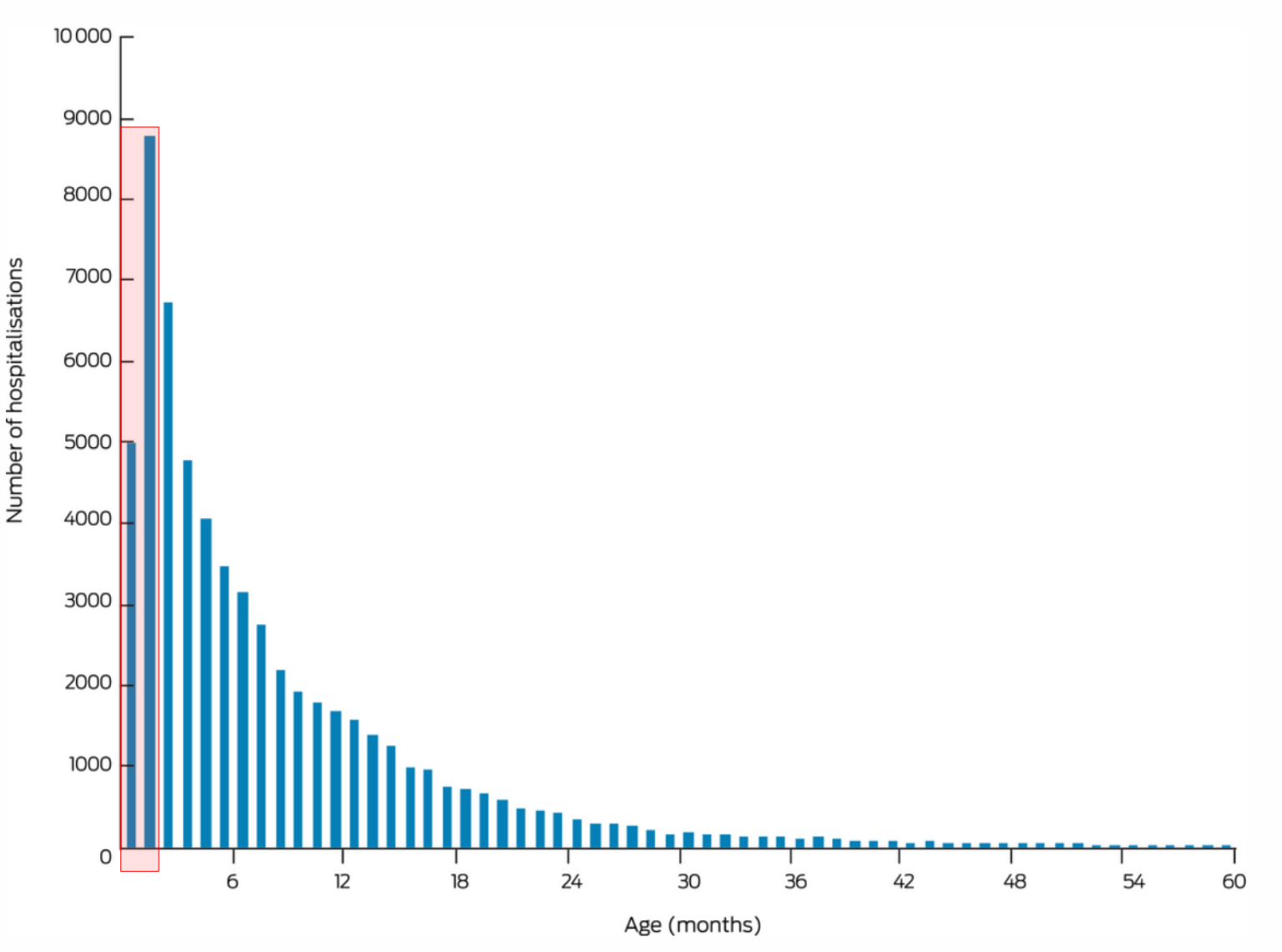
Christian Rosas-Salazar [1], Tatiana Chirkova [2], Tebeb Gebretsadik [3], James D Chappell [1], R Stokes Peebles Jr [4], William D Dupont [3], Samadhan J Jadhao [2], Peter J Gergen [5], Larry J Anderson [2], Tina V Hartert [6]

Abstract

Background: Early-life severe respiratory syncytial virus (RSV) infection has been associated with the onset of childhood wheezing illnesses. However, the relationship between RSV infection during infancy and the development of childhood asthma is unclear. We aimed to assess the association

"Not being infected with RSV during infancy was associated with a 26% lower risk of 5-year current asthma than being infected with RSV during infancy."

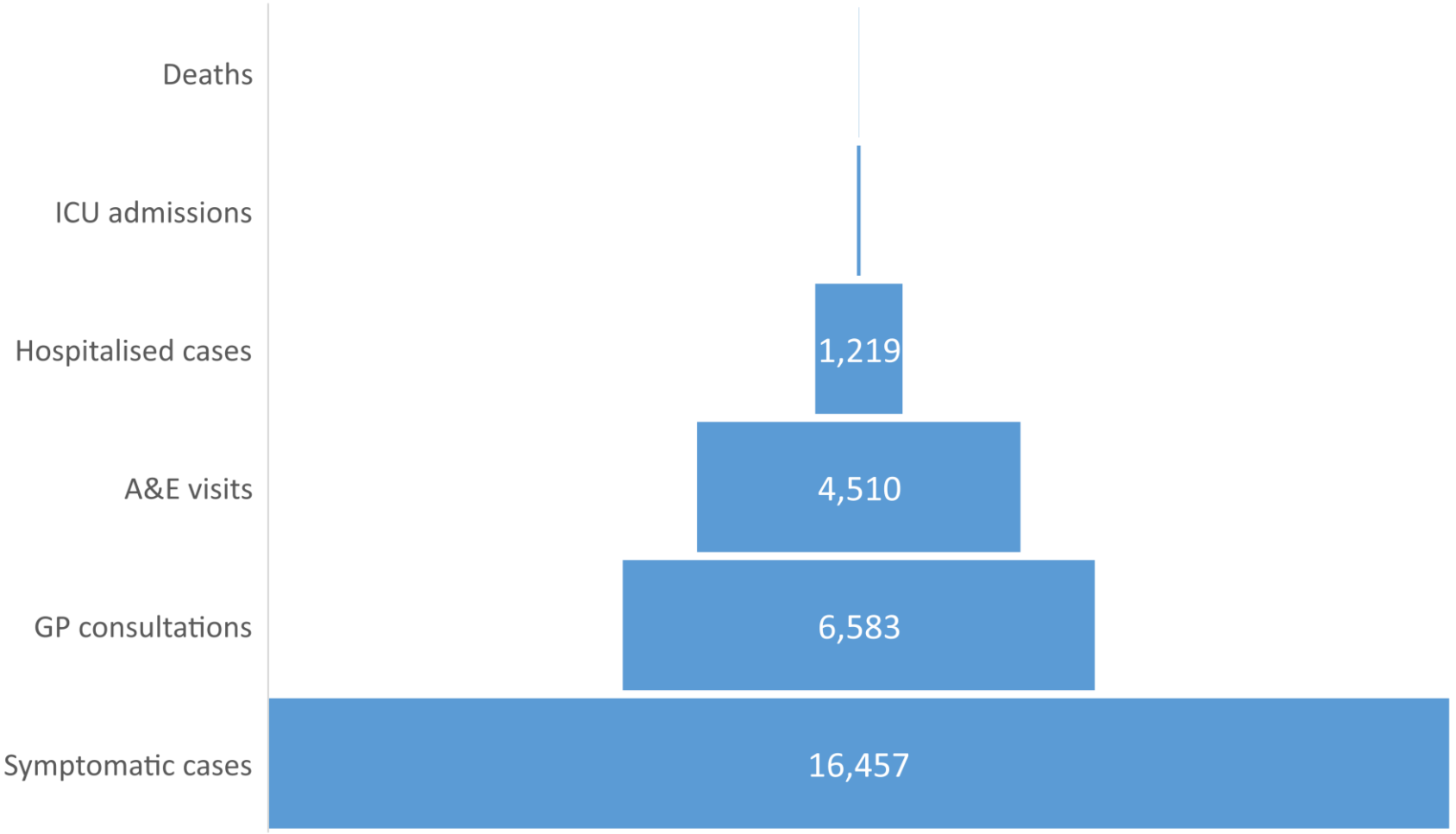
Number of RSV-coded hospitalisations (principal diagnosis only) of children under 5 years of age, Australia, 2006–2015



Hospitalised infants < 1 year of age

	Lab-proven RSV infections < 1 year of age
2023	993
2022	940

WA burden of illness pyramid (benchmarked off UK data)



Preventing RSV

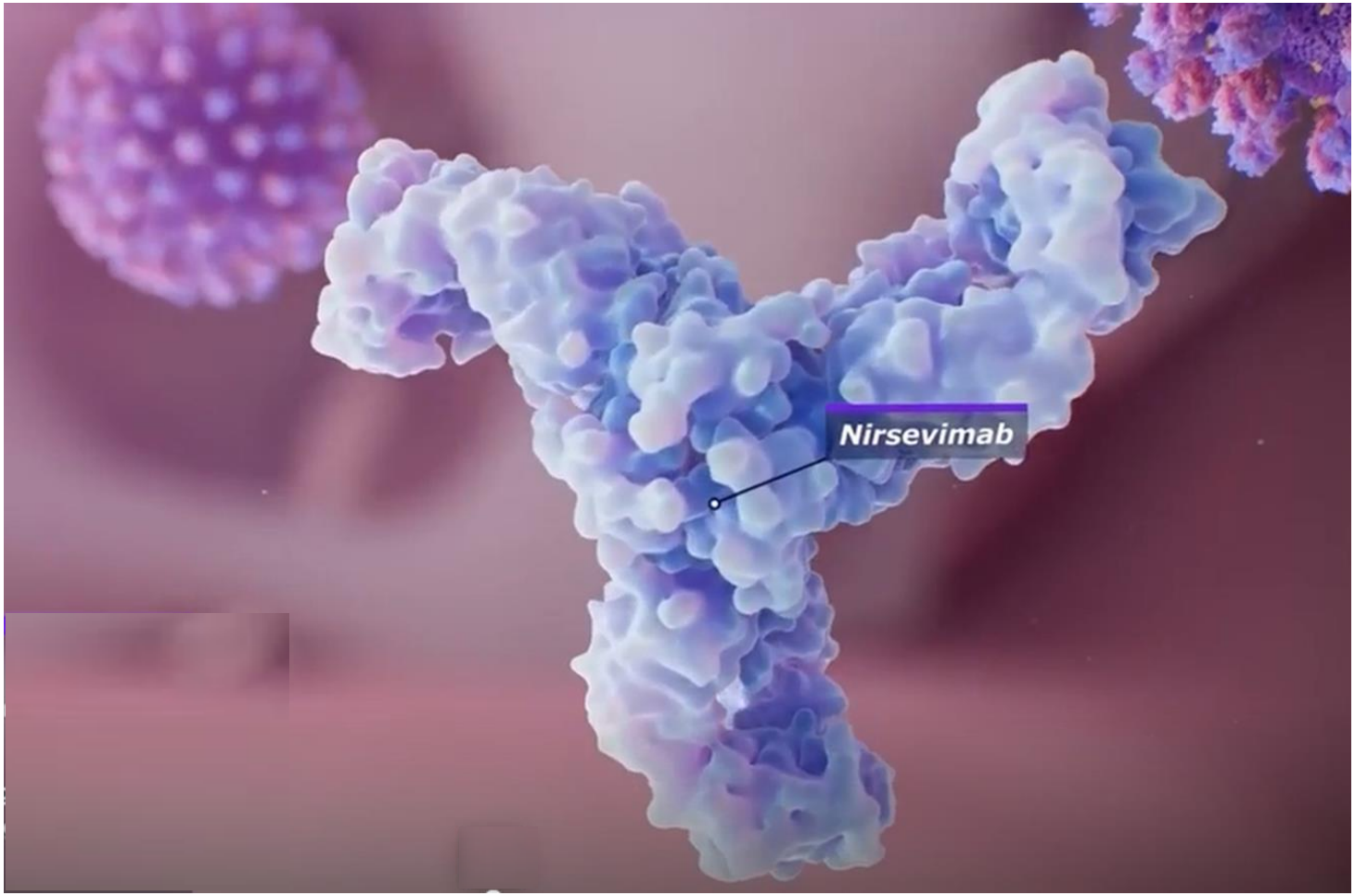
November 2023, TGA registered Nirsevimab (Beyfortus ®) – anti-RSV monoclonal antibody for infants.

This follows the registration in US, UK and EU earlier in 2023.

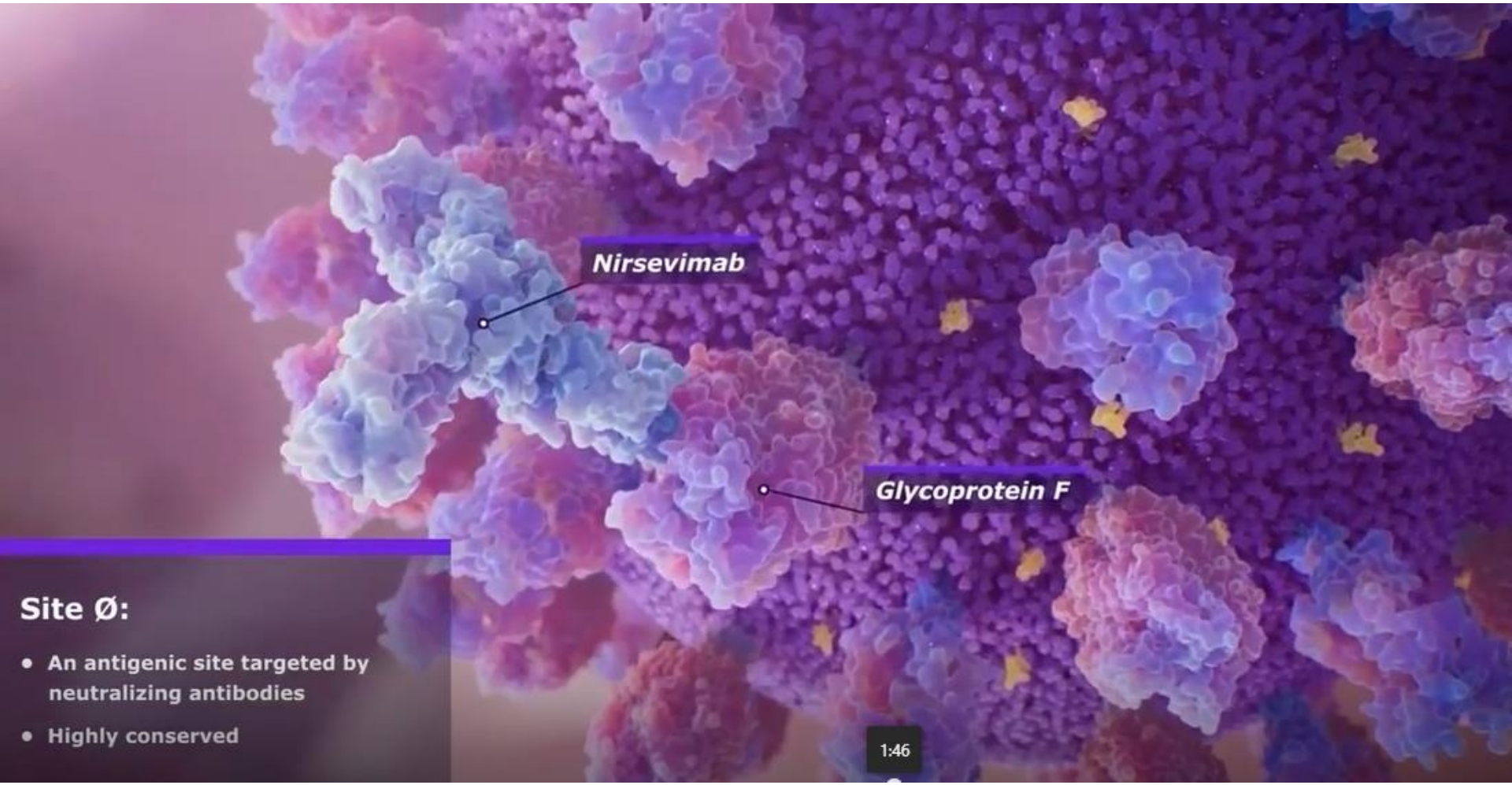
The indication is:

1. Infants old entering 1st RSV season (~8 months)
2. High-risk children entering second RSV season

Nirsevimab (Beyfortus)




RSV
Glycoprotein F


Nirsevimab
Glycoprotein F
Site Ø:
• An antigenic site targeted by neutralizing antibodies
• Highly conserved
1:46

Nirsevimab (Beyfortus)

- Not a vaccination but an immunisation using a human recombinant monoclonal antibody
- Binds to the fusion protein on the surface of the RSV virus to prevent infection
- Protection lasts 5 months (= one RSV season)

In addition to the nirsevimab antibody the product contains

- arginine hydrochloride
- histidine
- L-histidine hydrochloride monohydrate
- polysorbate 80
- sucrose and
- water for injection

Nirsevimab (Beyfortus)

In clinical trials Nirsevimab was shown to be:

- 79.0% effective at preventing medically attended RSV-associated lower respiratory tract infection (LRTI)
- 80.6% effective at preventing RSV-associated LRTI with hospitalization
- 90.0% effective at preventing RSV-associated LRTI with ICU admission.

Nirsevimab (Beyfortus)

Are there any real-world data on uptake and effectiveness?

Rapid communication

Impact of nirsevimab prophylaxis on paediatric respiratory syncytial virus (RSV)-related hospitalisations during the initial 2023/24 season in Luxembourg

Check for updates

Result of neonatal passive immunisation coverage estimation

Go to section...

Neonatal coverage in maternity wards from the beginning of October to mid-December 2023 was estimated at 84% (1,277 doses for 1,524 births) ranging from 66% to 94% between maternity wards. Coverage in outpatient settings could not be monitored as there is no immunisation registry. No adverse events associated with the immunisation have been reported to date.

84% neonatal uptake in maternity wards (range 66%- 94%)

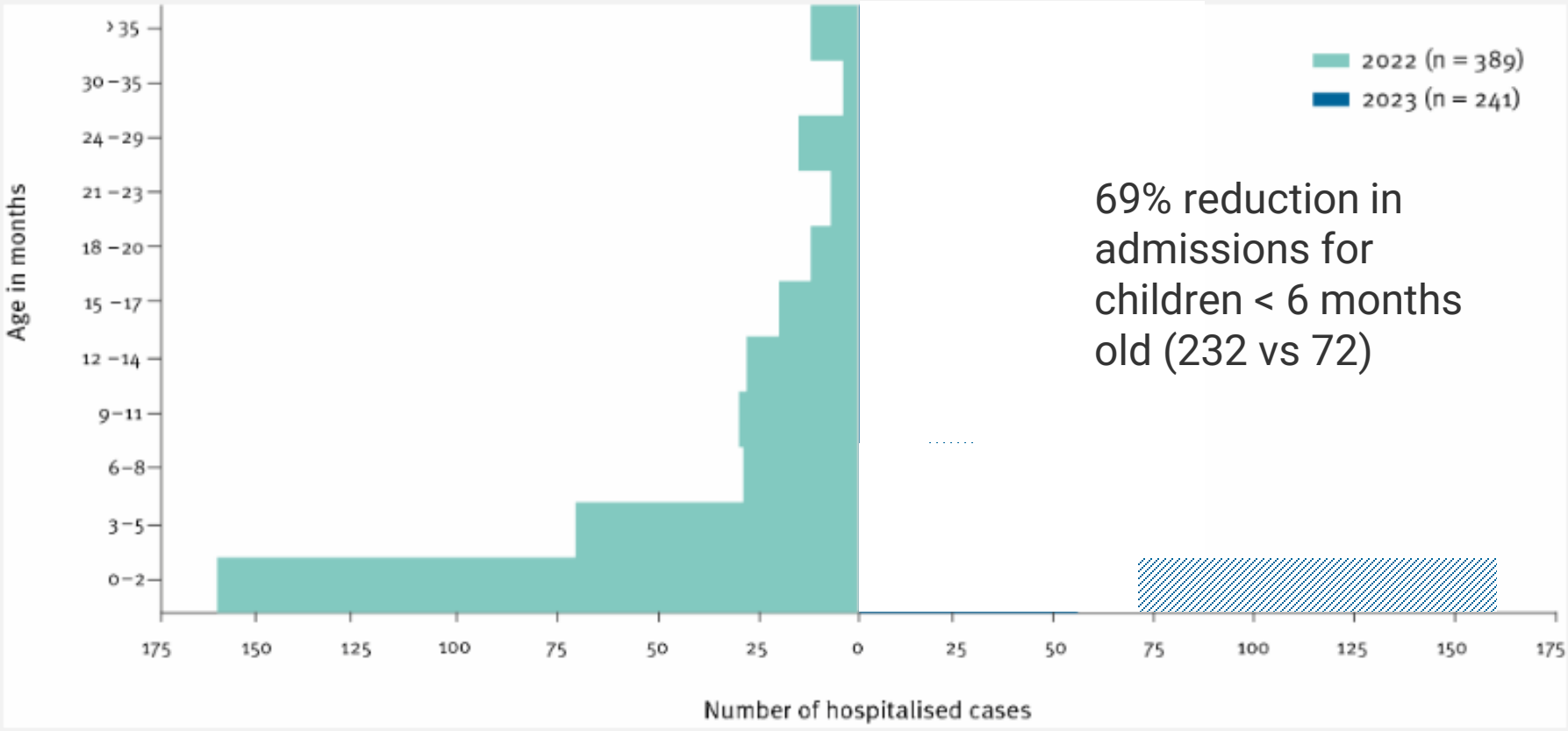
https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2024.29.4.2400033#html_fulltext

Rapid communication

Impact of nirsevimab prophylaxis on paediatric respiratory syncytial virus (RSV)-related hospitalisations during the initial 2023/24 season in Luxembourg

Check for updates

Figure 2. Age distribution of children hospitalised with respiratory syncytial virus (RSV) infection in Luxembourg's national paediatric hospital in weeks 39–52, Luxembourg, 2022–2023 (n = 630)



69% reduction in admissions for children < 6 months old (232 vs 72)

https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2024.29.4.2400033#html_fulltext

XUNTA DE GALICIA | DIRECCIÓN XERAL DE SAÚDE PÚBLICA

nirse-gal

Study

Evaluation of the effectiveness and impact of Nirsevimab in Galicia

The purpose of NIRSE-GAL is to evaluate the impact of the inclusion of nirsevimab in the Galician immunisation schedule on the prevention of Respiratory Syncytial Respiratory Syncytial Virus (RSV) infections in children.

View report

https://www.nirsegal.es/en

XUNTA DE GALICIA | DIRECCIÓN XERAL DE SAÚDE PÚBLICA

nirse-gal

85% coverage in the catch up cohort < 8 months

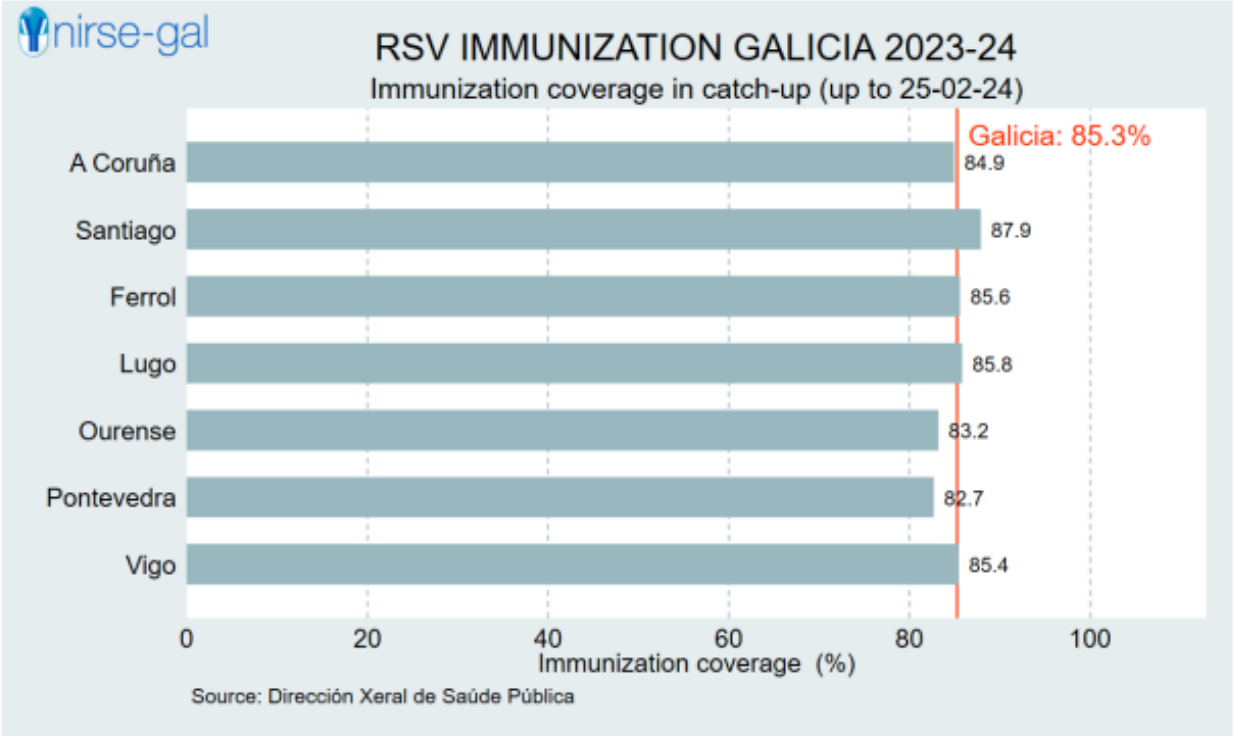


Figure 1. Immunization coverage in catch-up (born between 1 April and 24 September 2023), cummulative up to 25-02-2024, in Galicia by Health Area.

https://www.nirsegal.es/en

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nirse-gal

93% coverage in the birth cohort

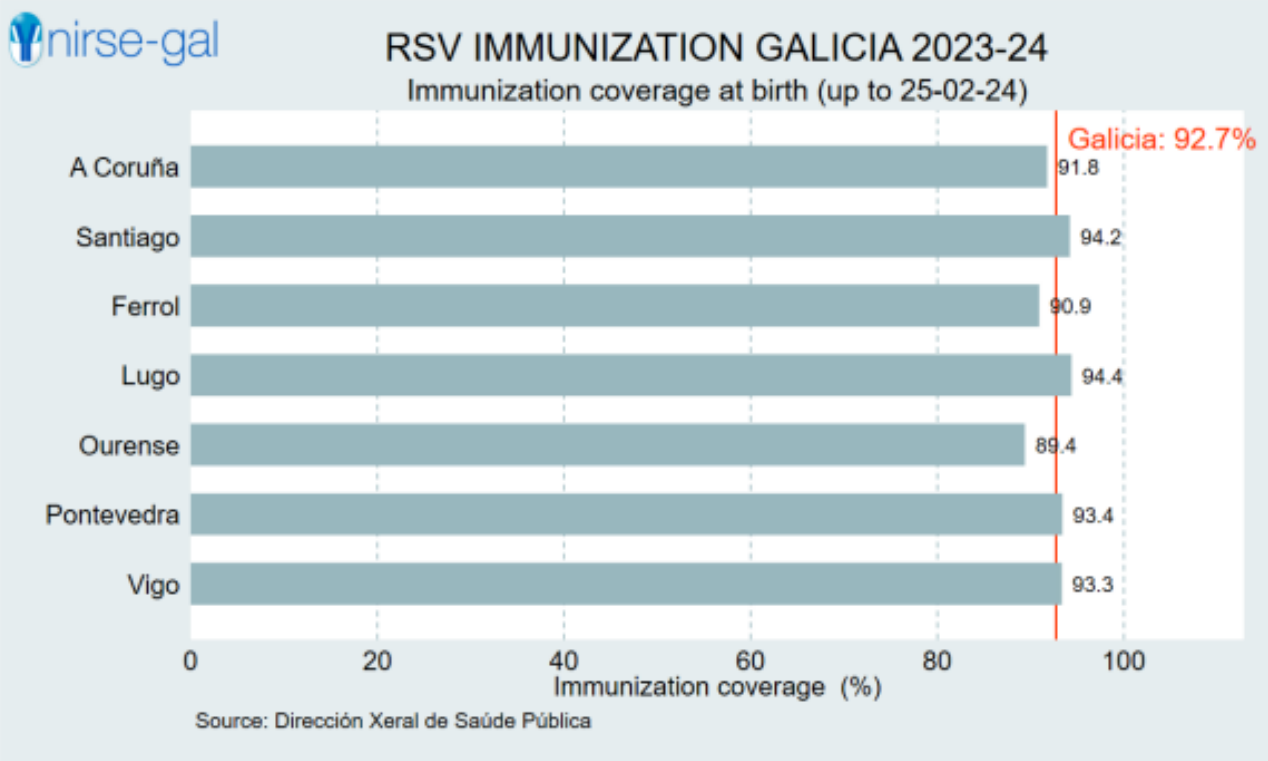

Figure 3. Immunization coverage at birth (births from 25-09-2023), in Galicia by Health Area. All births up to 18-02-2024 and all immunizations up to 25-02-2024.

https://www.nirsegal.es/en

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nirse-gal

Children 1-4 who mostly did not get nirsevimab

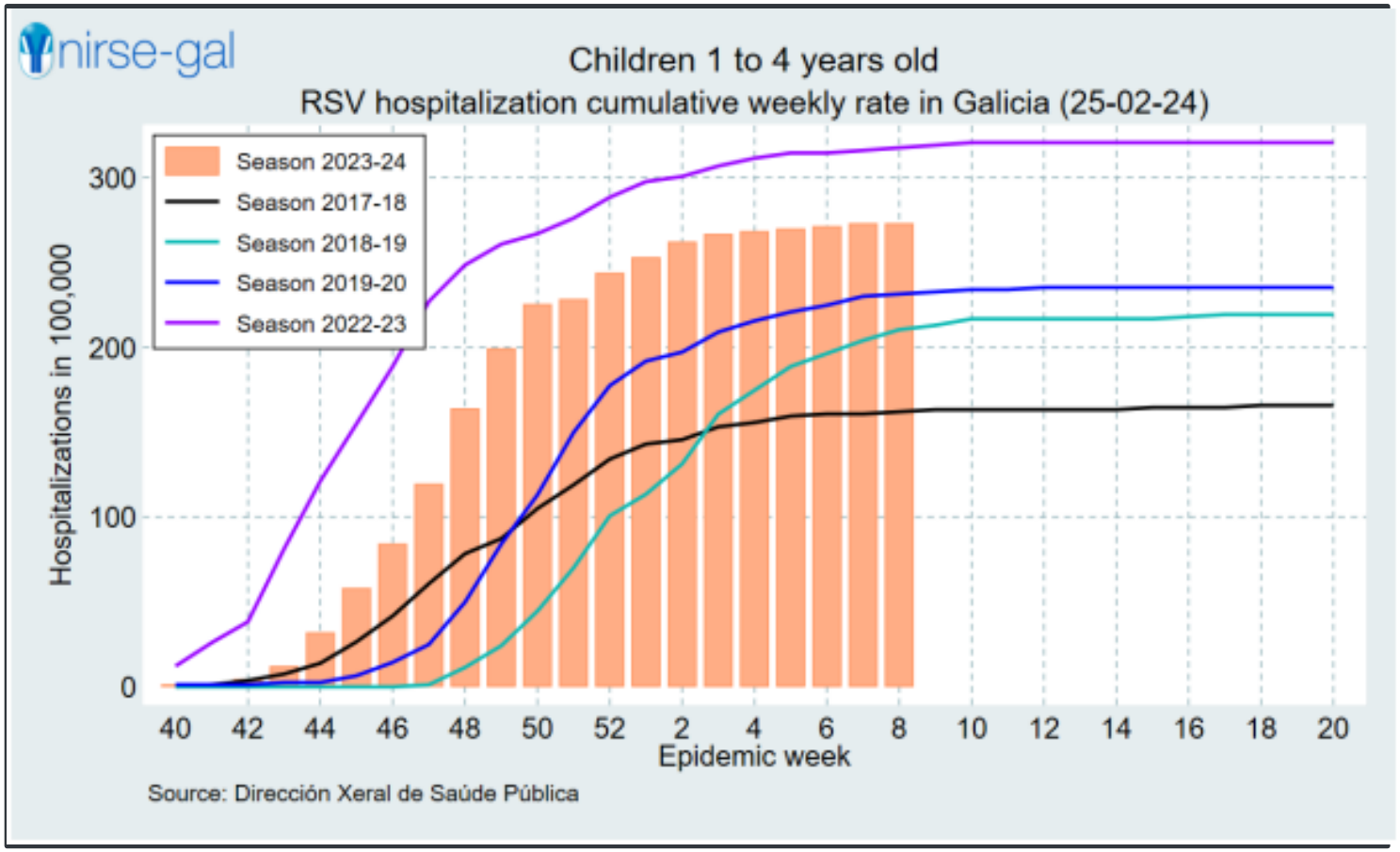


Figure 16. Cumulative weekly RSV hospitalization rate in Galicia, by season, up to, 25-02-2024. Children 1 to 4 years old.

https://www.nirsegal.es/en

XUNTA DE GALICIA | DIRECCIÓN XERAL DE SAÚDE PÚBLICA

nirse-gal

> 80% of children got nirsevimab

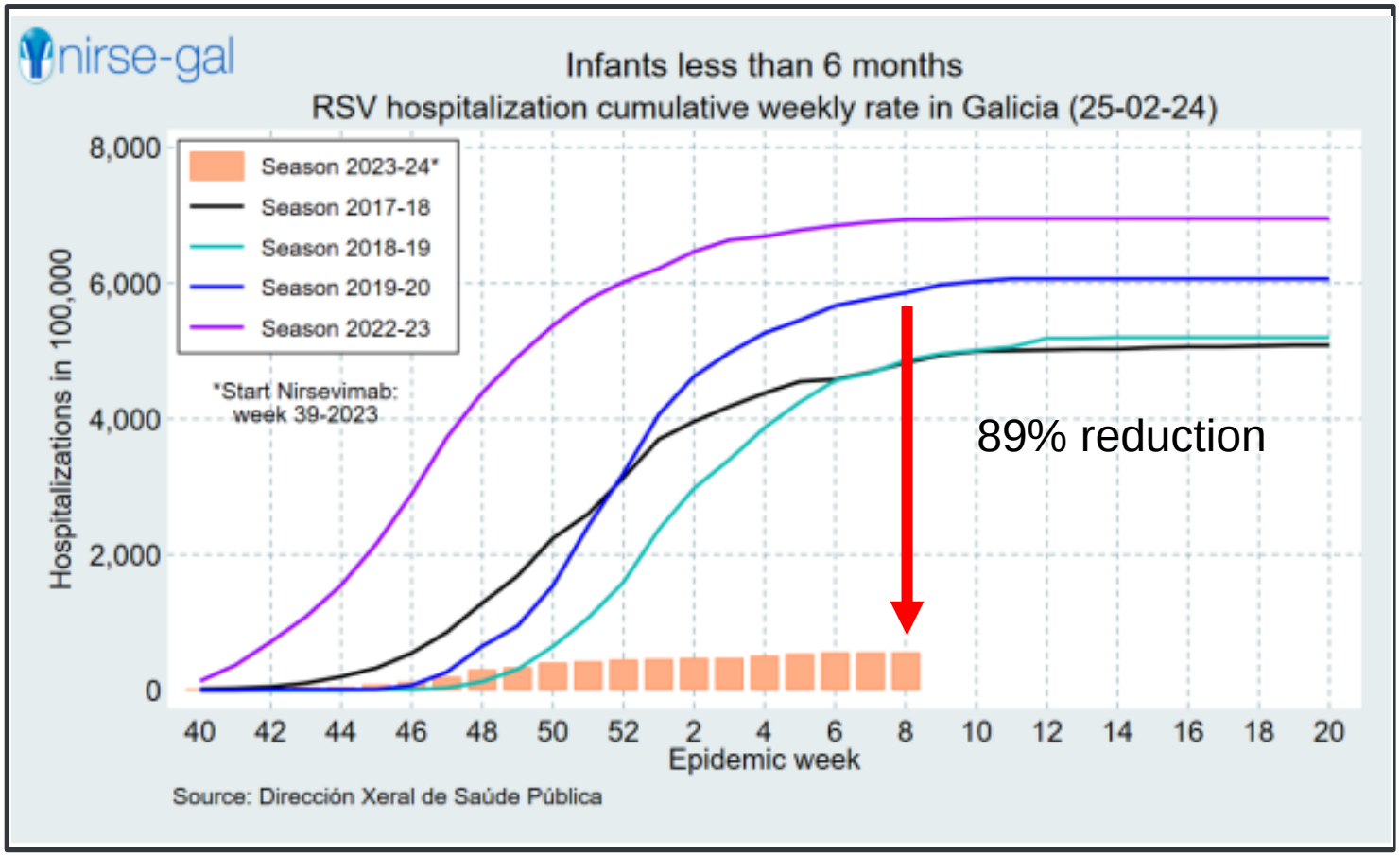


Figure 10. Cumulative weekly RSV hospitalization rate in Galicia, by season, up to 25-02-2024. Infants less than 6 months.

https://www.nirsegal.es/en

Morbidity and Mortality Weekly Report

Early Estimate of Nirsevimab Effectiveness for Prevention of Respiratory Syncytial Virus–Associated Hospitalization Among Infants Entering Their First Respiratory Syncytial Virus Season — New Vaccine Surveillance Network, October 2023–February 2024

Heidi L. Moline, MD[1]; Ayzsa Tannis, MPH[1]; Ariana P. Toepfer, MPH[1]; John V. Williams, MD[2,3]; Julie A. Boom, MD[4,5]; Janet A. Englund, MD[6]; Natasha B. Halasa, MD[7]; Mary Allen Staat, MD[8,9]; Geoffrey A. Weinberg, MD[10]; Rangaraj Selvarangan, PhD[11]; Marian G. Michaels, MD[2,3]; Leila C. Sahni, PhD[4,5]; Eileen J. Klein, MD[6]; Laura S. Stewart, PhD[7]; Elizabeth P. Schlaudecker, MD[8,9]; Peter G. Szilagyi, MD[10]; Jennifer E. Schuster, MD[12]; Leah Goldstein, MPH[1]; Samar Musa, MPH[2,3]; Pedro A. Piedra, MD[4,5]; Danielle M. Zerr, MD[6]; Kristina A. Betters, MD[7]; Chelsea Rohlfs, MBA[9]; Christina Albertin, MPH[10]; Dithi Banerjee, PhD[12]; Erin R. McKeever, MPH[1]; Casey Kalman, MPH[1]; Benjamin R. Clopper, MPH[1]; New Vaccine Surveillance Network Product Effectiveness Collaborators; Meredith L. McMorrow, MD[1,*]; Fatimah S. Dawood, MD[1,*]

Abstract

Respiratory syncytial virus (RSV) is the leading cause of hospitalization among infants in the United States. In August 2023, CDC's Advisory Committee on Immunization Practices

highest hospitalization rates occur during the first months of life, and risk declines with increasing age in infancy and during early childhood (*3*). In August 2023, CDC's Advisory Committee on Immunization Practices (ACIP) recommended

The New Vaccine Surveillance Network: 1 Oct 2023– 29 February 2024.

Nirsevimab effectiveness was **90%** (95% CI = 75%–96%) against RSV associated hospitalization.

Effectiveness of Nirsevimab Immunoprophylaxis Against Respiratory Syncytial Virus-Related Outcomes in Hospital and Primary Care Settings: A Retrospective Cohort Study in Infants in Catalonia (Spain)

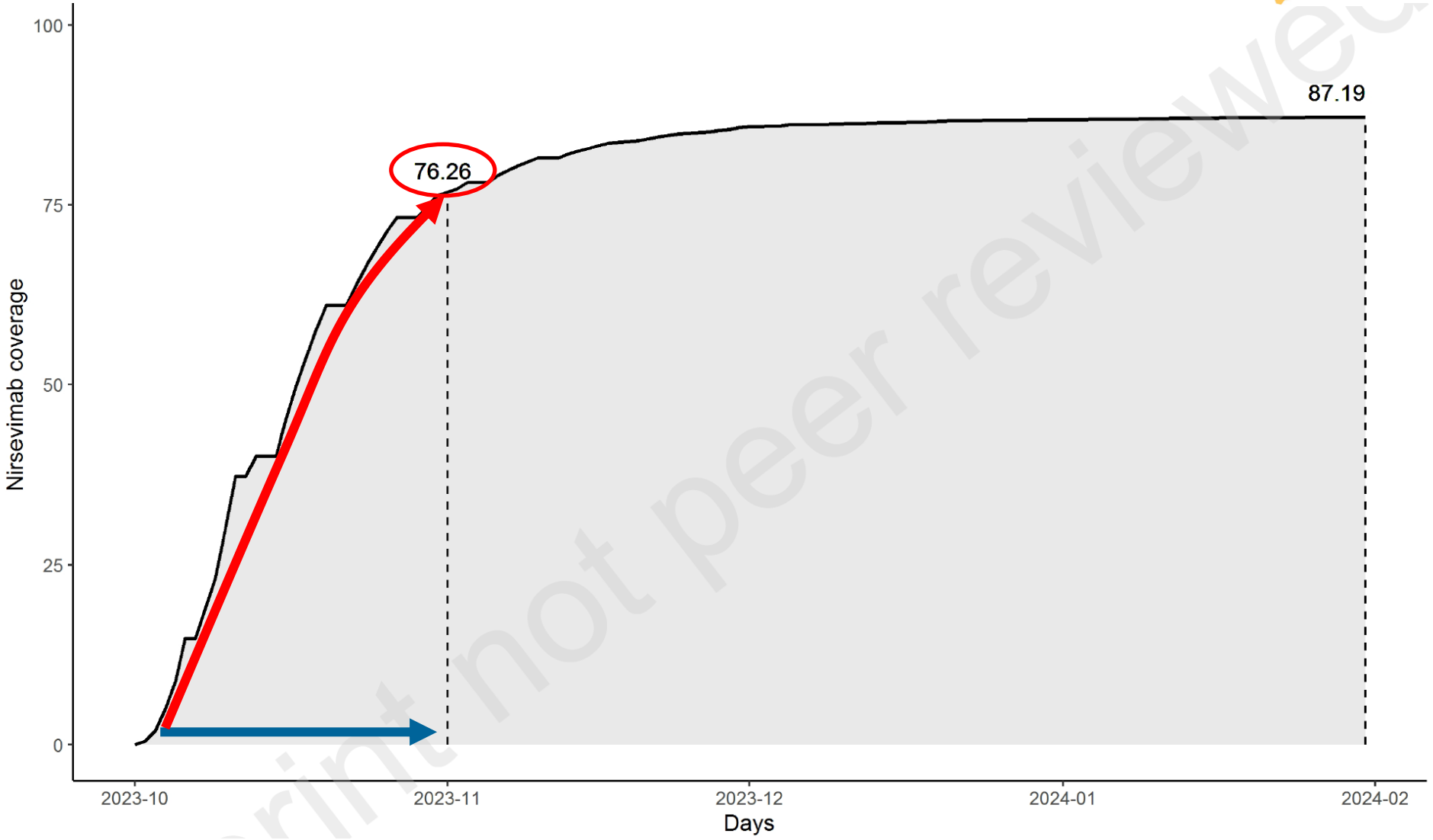
17 Pages • Posted: 7 Mar 2024

Ermengol Coma
Institut Català de la Salut - Sistemes d'Informació dels Serveis d'Atenció Primària (SISAP)

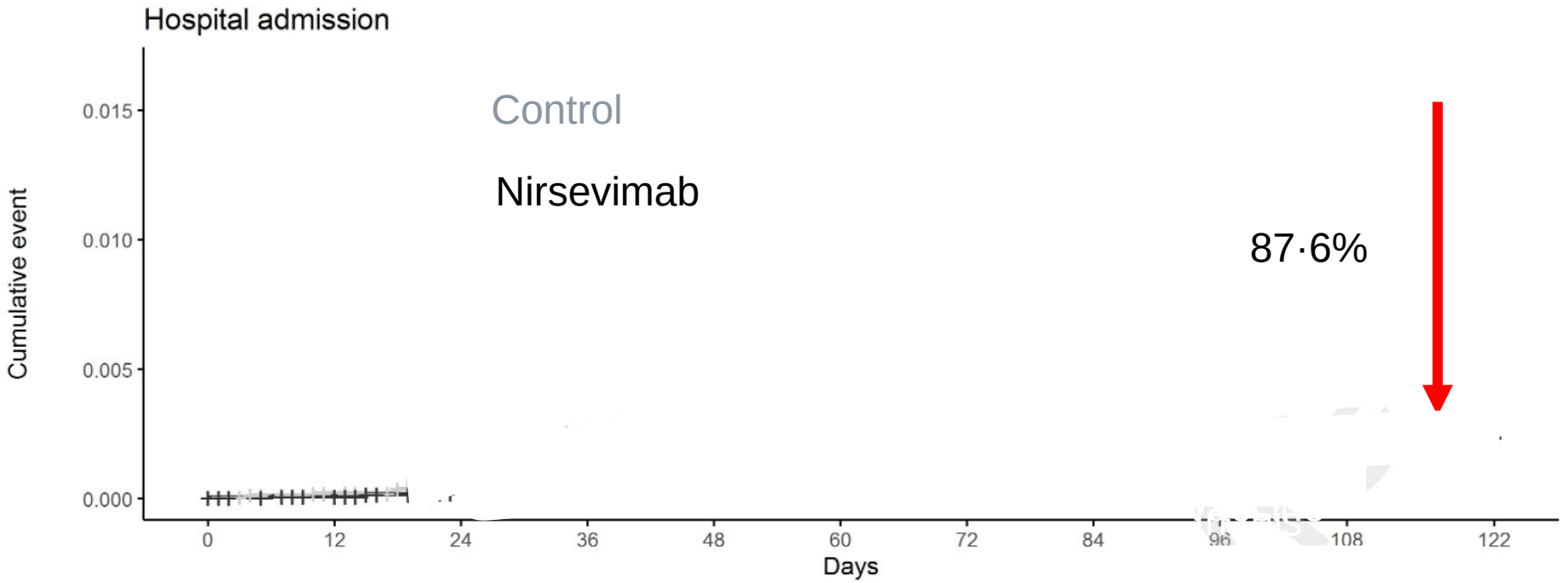
Infants immunised with Nirsevimab N=23,127 (87%)

Infants not immunised N=3,398 (13%)

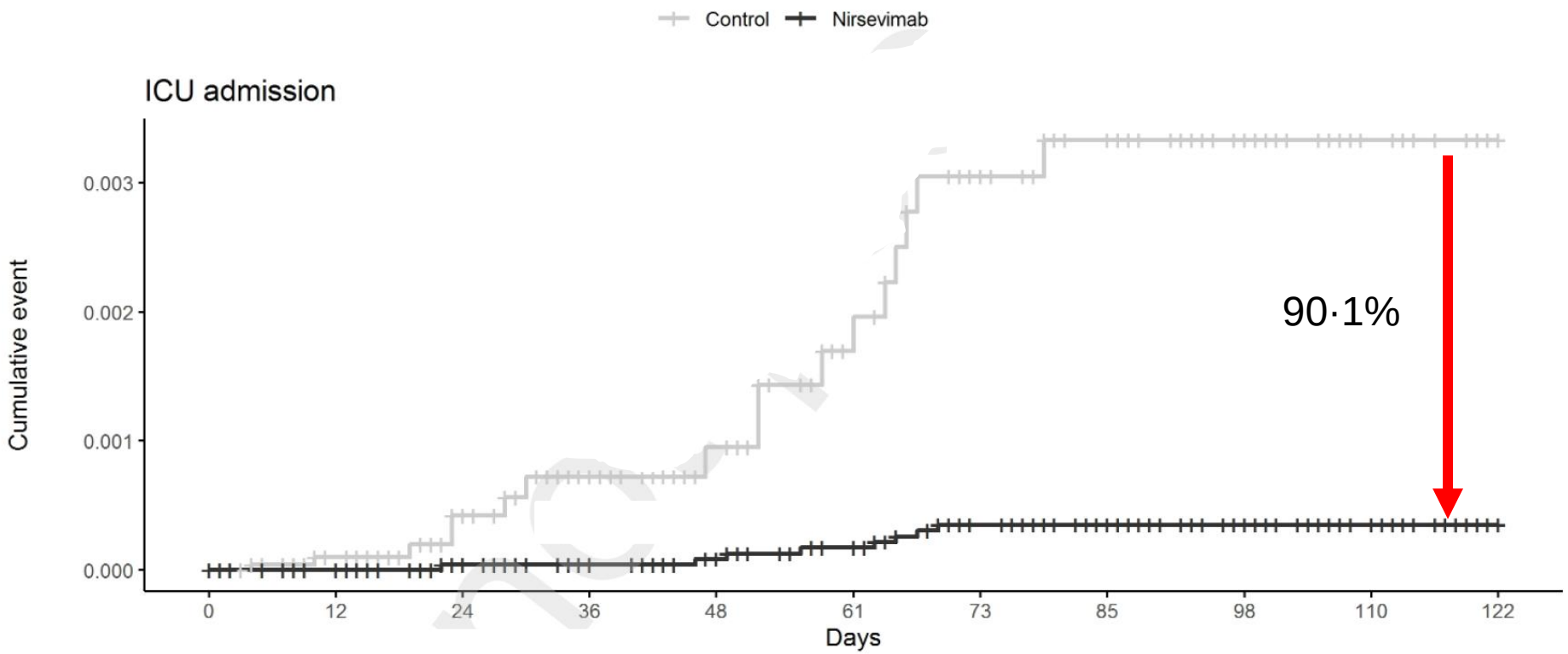
Nirsevimab Effectiveness Against RSV-Related Outcomes among Infants in Catalonia (Spain)



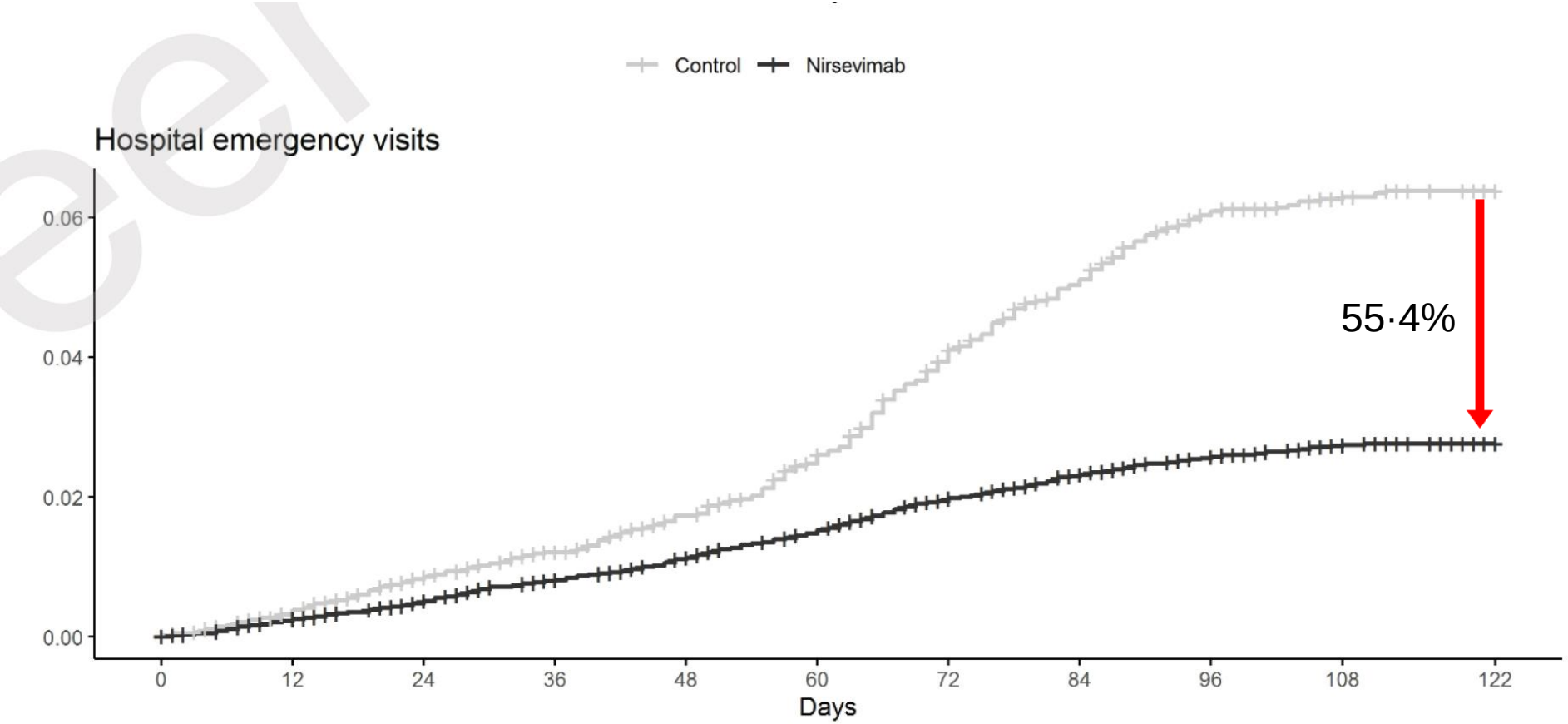
RSV-Associated Hospital Admissions



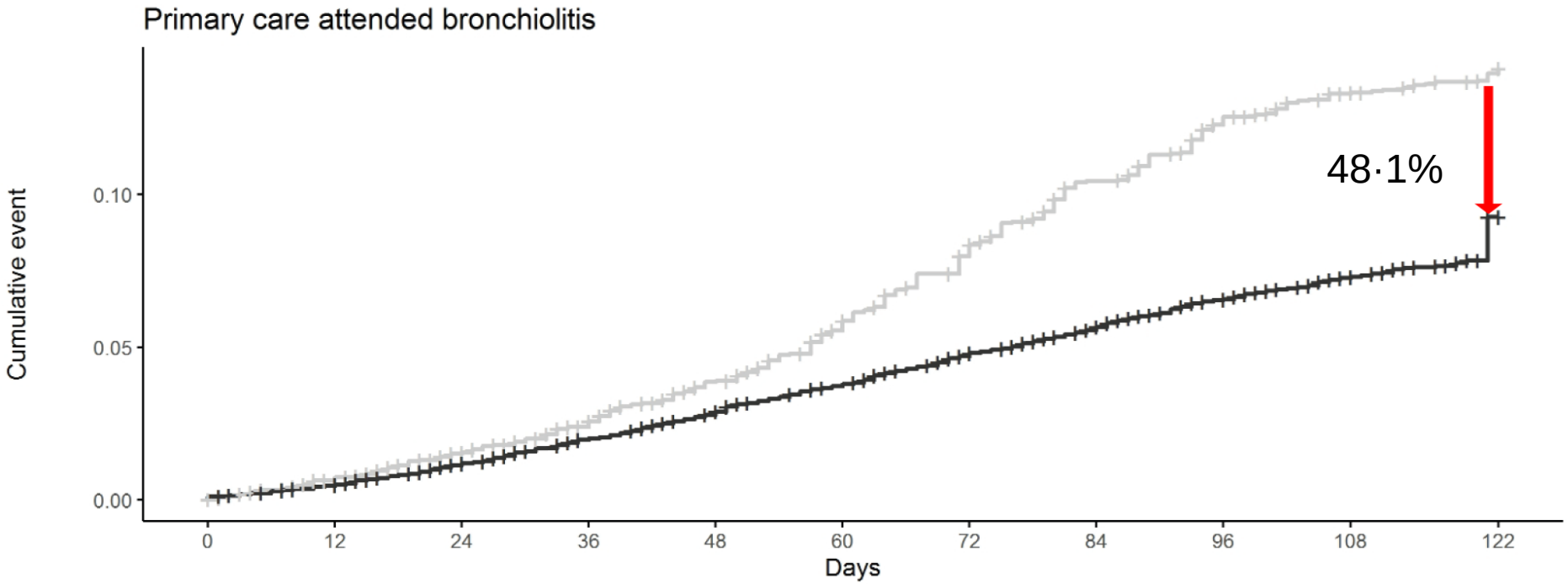
RSV-Associated ICU Admissions



Bronchiolitis - Emergency Department Visits



Bronchiolitis - Primary Care Attended



Is Nirsevimab safe?

Nirsevimab clinical trial safety data

Table 2 **Adverse Reactions Reported at an Incidence Higher Than Placebo in the Safety Population* (Trials 03 and 04)**

Adverse Reaction	BEYFORTUS N=2,570 %	Placebo N=1,284 %
Rash† (occurring within 14 days post-dose)	0.9	0.6
Injection site reaction‡ (occurring within 7 days post-dose)	0.3	0

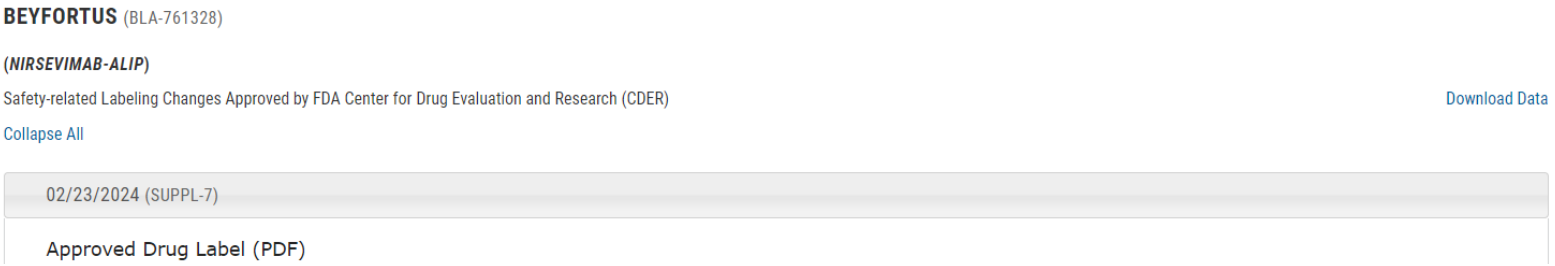
* The Safety Population includes all subjects who received the recommended dose of BEYFORTUS in Trials 03 and 04: Primary and Safety cohorts from Trial 04; infants who weighed less than 5 kg and who received the recommended dose of BEYFORTUS (single 50 mg IM dose) in Trial 03.

† Rash was defined by the following grouped preferred terms: rash, rash macular, rash maculo-papular, rash papular.

‡ Injection site reaction was defined by the following grouped preferred terms: injection site reaction, injection site pain, injection site induration, injection site edema, injection site swelling.

In clinical trials when Nirsevimab was given with routine childhood vaccines, the safety and reactogenicity profile of the co-administered regimen was similar to the childhood vaccines given alone.

Nirsevimab post-marketing surveillance



BEYFORTUS (BLA-761328)

(NIRSEVIMAB-ALIP)

Safety-related Labeling Changes Approved by FDA Center for Drug Evaluation and Research (CDER)

Download Data

Collapse All

02/23/2024 (SUPPL-7)

Approved Drug Label (PDF)

"Serious hypersensitivity reactions have been reported following BEYFORTUS administration. These reactions included urticaria, dyspnea, cyanosis, and/or hypotonia. Anaphylaxis has been observed with human immunoglobulin G1 (IgG1) monoclonal antibodies."

"Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure."

FDA Adverse Events Reporting System (FAERS) Public Dashboard

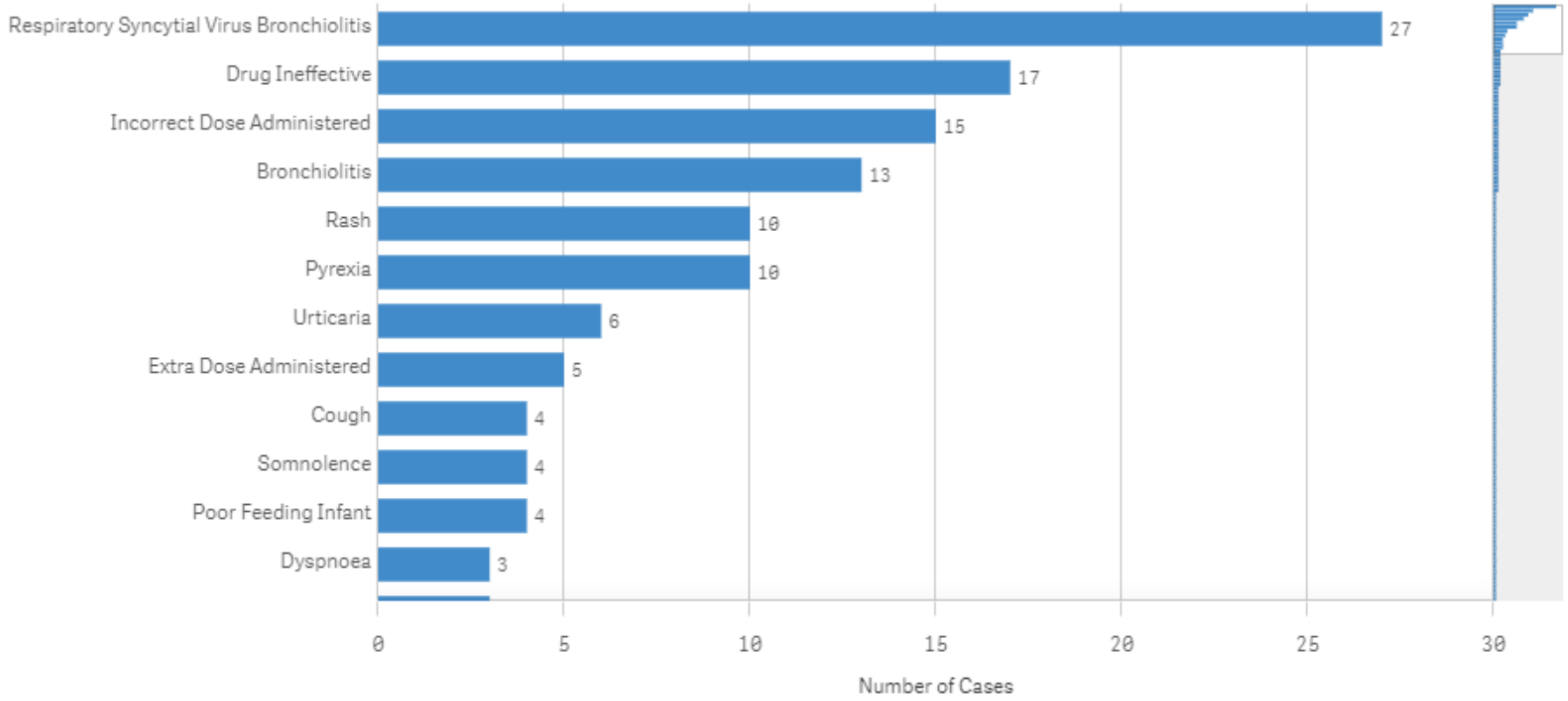
Home | Demographics | Reaction Group | Reaction | Listing of Cases

NIRSEVIMAB (G); NIRSEVIMAB-ALIP (G)

Total Cases
144

Data as of 31 Dec 2023

Case Count by Reaction



1.4 million doses of nirsevimab distributed in the US – 144 adverse event reports

Nirsevimab post-marketing surveillance

	A	C	D	E	F
1	Case ID	Suspect Product Active Ingredi	Reason for Use	Reactions	Paul's grouping
2	23226879	Nirsevimab-Alip	-	Eczema;Rash	Allergic reaction likely
3	23128838	Nirsevimab-Alip	Antiviral Prophylaxis	Petechiae;Rash	Allergic reaction likely
4	23302362	Nirsevimab-Alip	-	Rash	Allergic reaction likely
5	23094910	Nirsevimab-Alip	Respiratory Syncytial Virus Immunisation	Rash	Allergic reaction likely
6	23114857	Nirsevimab-Alip	-	Swelling	Allergic reaction likely
7	23094424	Nirsevimab-Alip	-	Swelling;Urticaria	Allergic reaction likely
8	23120053	Nirsevimab-Alip	Immunisation	Urticaria	Allergic reaction likely
9	23128594	Nirsevimab-Alip	Antiviral Prophylaxis	Dermatitis Exfoliative Generalised;Oral Mucosal Exfoliation;Skin Exfoliation;Rash Papular	Allergic reaction likely
10	23272713	Nirsevimab-Alip	Respiratory Syncytial Virus Immunisation	Rash;Gastroenteritis	Allergic reaction likely
11	23351586	Nirsevimab-Alip	-	Bronchitis;Cough;Gastrooesophageal Reflux Disease;Wheezing;Lip Swelling;Sleep Disorder;Drug Interaction;Anaphylactic Reaction;Urticaria	Allergic reaction likely
12	23105392	Nirsevimab-Alip	Respiratory Syncytial Virus Immunisation	Erythema Multiforme	Allergic reaction likely
13	23351727	Nirsevimab-Alip	Immunisation	Erythema Multiforme;Adverse Event Following Immunisation	Allergic reaction likely
14	23139714	Nirsevimab-Alip	-	Erythema Multiforme;Adverse Event Following Immunisation	Allergic reaction likely
15	23219063	Nirsevimab-Alip	Antiviral Prophylaxis	Lymphopenia;Neutropenia;Rash	Allergic reaction likely
16	23176796	Nirsevimab-Alip	-	Rash	Allergic reaction likely
17	23125226	Nirsevimab-Alip	Antiviral Prophylaxis	Rash;Hypersensitivity	Allergic reaction likely
18	23267699	Nirsevimab-Alip	Antiviral Prophylaxis	Rash;Injection Related Reaction;Urticaria	Allergic reaction likely
19	23285170	Nirsevimab-Alip;Diphtheria An	Antiviral Prophylaxis;Immunisation;Reflux Gast	Urticaria	Allergic reaction likely
20	23138326	Nirsevimab-Alip	-	Urticaria;Viral Rash	Allergic reaction likely
21	23196918	Nirsevimab-Alip	Respiratory Syncytial Virus Immunisation	Apnoea;Oxygen Saturation Decreased	Apnoea
22	23098144	Nirsevimab-Alip	Respiratory Syncytial Virus Infection	Respiratory Syncytial Virus Infection	Break through bronchiolitis
23	23285105	Nirsevimab-Alip	Immunisation	Respiratory Syncytial Virus Infection;Drug Ineffective	Break through bronchiolitis
24	23321647	Nirsevimab-Alip	Immunisation	Bronchiolitis;Drug Ineffective	Break through bronchiolitis
25	23285333	Nirsevimab-Alip	Immunisation	Bronchiolitis;Drug Ineffective	Break through bronchiolitis
26	23238810	Nirsevimab-Alip	Immunisation	Bronchiolitis;Drug Ineffective	Break through bronchiolitis
27	23222141	Nirsevimab-Alip	Antiviral Prophylaxis	Bronchiolitis;Drug Ineffective	Break through bronchiolitis
28	23196956	Nirsevimab-Alip	-	Bronchiolitis;Vomiting	Break through bronchiolitis
29	23138539	Nirsevimab-Alip	Antiviral Prophylaxis	Diarrhoea;Vomiting;Upper Respiratory Tract Infection	Break through bronchiolitis
30	23286723	Nirsevimab-Alip	Immunisation	Drug Ineffective;Bronchiolitis	Break through bronchiolitis
31	23285165	Nirsevimab-Alip	Immunisation	Drug Ineffective;Bronchiolitis	Break through bronchiolitis
32	23263089	Nirsevimab-Alip	-	Drug Ineffective;Bronchiolitis	Break through bronchiolitis
33	23242273	Nirsevimab-Alip	Immunisation	Drug Ineffective;Bronchiolitis	Break through bronchiolitis
34	23221922	Nirsevimab-Alip	Antiviral Prophylaxis	Drug Ineffective;Bronchiolitis	Break through bronchiolitis
35	23291545	Nirsevimab-Alip	Prophylaxis	Drug Ineffective;Respiratory Syncytial Virus Bronchiolitis	Break through bronchiolitis
36	23133145	Nirsevimab-Alip	Congenital Nephrotic Syndrome;High Risk Infar	Moraxella Infection;Respiratory Tract Infection;Anaemia;Pyrexia;Acute Respiratory Failure	Break through bronchiolitis
37	23176798	Nirsevimab-Alip	Infant;Prophylaxis	Respiratory Distress;Respiratory Syncytial Virus Test Positive;Human Rhinovirus Test Positive	Break through bronchiolitis
38	23285313	Nirsevimab-Alip	Antiviral Prophylaxis	Respiratory Syncytial Virus Bronchiolitis	Break through bronchiolitis

Nirsevimab Administration

- As a monoclonal antibody Nirsevimab is not expected to interfere with the active immune response to co-administered vaccines.
- Can be co-administered with other vaccines.

Does getting Nirsevimab as a young infant simply push a serious RSV illness out to your second RSV season?

Clinical Trial > J Pediatric Infect Dis Soc. 2024 Feb 26;13(2):144-147. doi: 10.1093/jpids/piad113.

Infants Receiving a Single Dose of Nirsevimab to Prevent RSV Do Not Have Evidence of Enhanced Disease in Their Second RSV Season

Ron Dagan [1], Laura L Hammitt [2], Beatriz Seoane Nuñez [3], Manuel Baca Cots [4], Miroslava Bosheva [5], Shabir A Madhi [6], William J Muller [7 8], Heather J Zar [9], Yue Chang [10], Alexander Currie [11], Amy Grenham [10], Manish Shroff [12], Therese Takas [10], Vaishali S Mankad [13], Amanda Leach [10], Tonya Villafana [10]

Affiliations + expand

PMID: 38219024 PMCID: PMC10896255 DOI: 10.1093/jpids/piad113

Free PMC article

Abstract

To characterize nirsevimab in the prevention of RSV, children from the Phase 3 MELODY trial were followed through their second RSV season. No increase in medically attended RSV lower respiratory tract infections or evidence of antibody-dependent enhancement of infection or disease severity was found for nirsevimab vs placebo recipients. Clinical Trial Registration: Clinicaltrials.gov, NCT03979313, https://clinicaltrials.gov/ct2/show/NCT03979313.

https://pubmed.ncbi.nlm.nih.gov/38219024/

How does that work?

Nat Med. 2023 May;29(5):1172-1179. doi: 10.1038/s41591-023-02316-5. Epub 2023 Apr 24.

Durability of neutralizing RSV antibodies following nirsevimab administration and elicitation of the natural immune response to RSV infection in infants

Deidre Wilkins [1], Yuan Yuan [2], Yue Chang [2], Anastasia A Aksyuk [2], Beatriz Seoane Núñez [3], Ulrika Wählby-Hamrén [4], Tianhui Zhang [5], Michael E Abram [2], Amanda Leach [6], Tonya Villafana [7], Mark T Esser [7]

Affiliations + expand

PMID: 37095249 PMCID: PMC10202809 DOI: 10.1038/s41591-023-02316-5

Free PMC article

Abstract

"In summary, nirsevimab provided sustained, high levels of NAb throughout an infant's first RSV season and prevented RSV **disease** while allowing the development of an immune response to RSV."

https://pubmed.ncbi.nlm.nih.gov/37095249/

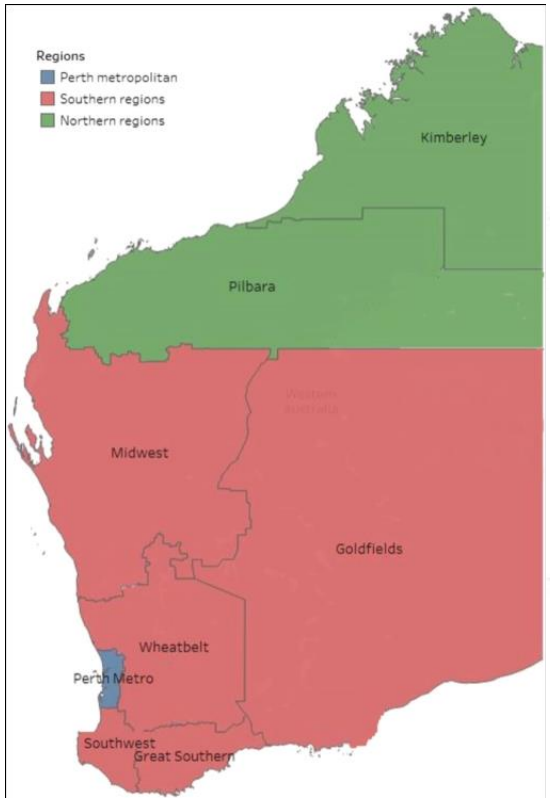
What might the impact be in WA?

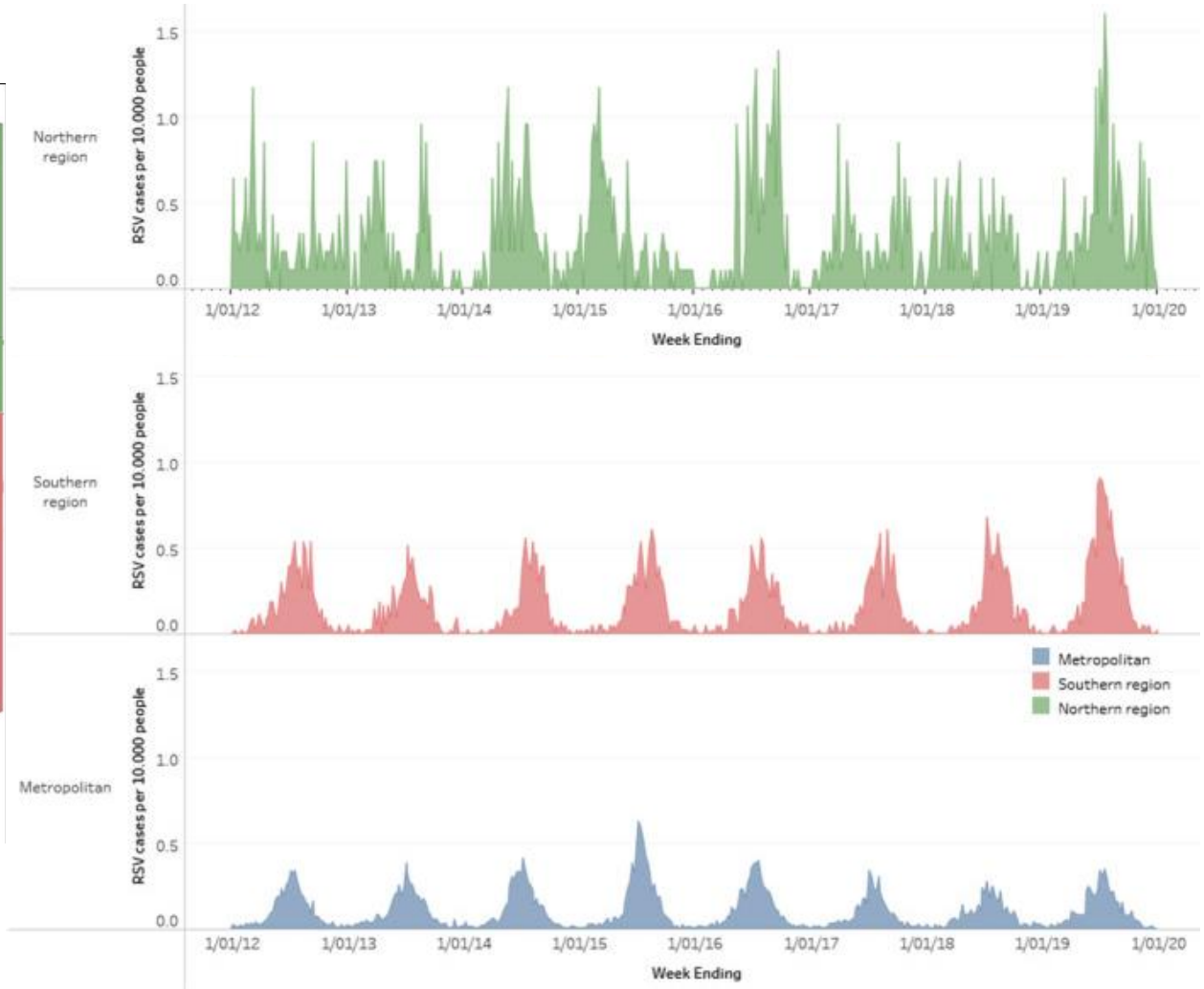
	Hospitalised infants < 1 year of age		
	Lab-proven RSV infections < 1 year of age	Pneumonia, Acute bronchitis, Acute bronchiolitis due to RSV (J12.1- J20.5- J21.0)	Plus 80% of admissions Acute bronchiolitis, unspecified (J21.9)
2023	993	1,028	1,333
2022	940	1,035	1,350

	Hospitalised infants < 1 year of age		
	Lab-proven RSV infections < 1 year of age	Pneumonia, Acute bronchitis, Acute bronchiolitis due to RSV (J12.1- J20.5- J21.0)	Plus 80% of admissions Acute bronchiolitis, unspecified (J21.9)
2023	993	1,028	1,333
2022	940	1,035	1,350
Hospitalisations prevented with 80% coverage & 80% effectiveness			
	636	658	853
	602	662	864
Range	619	660	859

When should we start?

Seasonality of RSV in WA: 2012-2019





https://onlinelibrary.wiley.com/doi/full/10.1111/irv.13117

Government of **Western Australia**
Department of **Health**

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Notifiable infectious disease dashboard

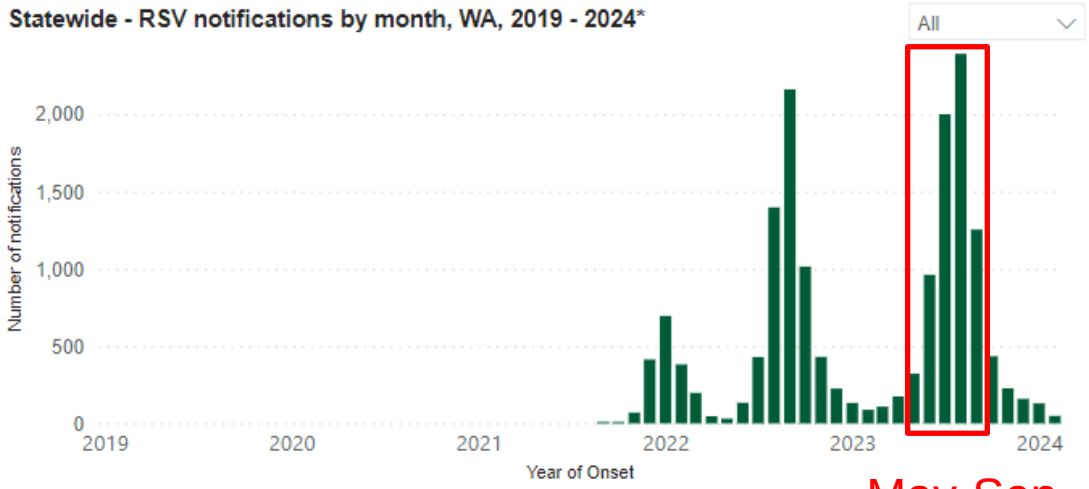
Select a disease: RSV **Select a year:** 2023

Statewide YTD (2024)
179
5-Year YTD average (2019 - 2023) = 213

Statewide Male to Female Rate Ratio (2023)
1.1 : 1
Rate per 100,000 population

Statewide Aboriginal to Non-Aboriginal Rate Ratio (2023)
2.1 : 1
Rate per 100,000 population

Statewide - RSV notifications by month, WA, 2019 - 2024*



May-Sep

Statewide - RSV notifications and rates by year, WA, 2019 - 2024*

Year	Number	Rate
2019		0.0
2020		0.0
2021	492	18.6
2022	7,150	267.7
2023	8,259	307.1
2024*	179	39.7

Respiratory syncytial virus (RSV) became a notifiable infectious disease in August 2021

https://www.health.wa.gov.au/articles/n_r/notifiable-infectious-disease-dashboard

Nirsevimab Administration

- IM injection – like most vaccines
- Same cold chain 2-8 C
- 8 hours at room temp (20-25 C)
- Pre-filled syringe

Nirsevimab Administration

- But 2 different doses

50mg (0.5 mL) for < 5kg

100mg (1.0 mL) for >= 5kg

Nirsevimab Administration

Three pronged roll-out for 2024 (if we go ahead)

a) GPs, AMS, CACHS/WACHS: April catch-up of all infants born on or after 1 Oct 2023

b) Birthing hospitals: all infants born during RSV season (May-Sep)

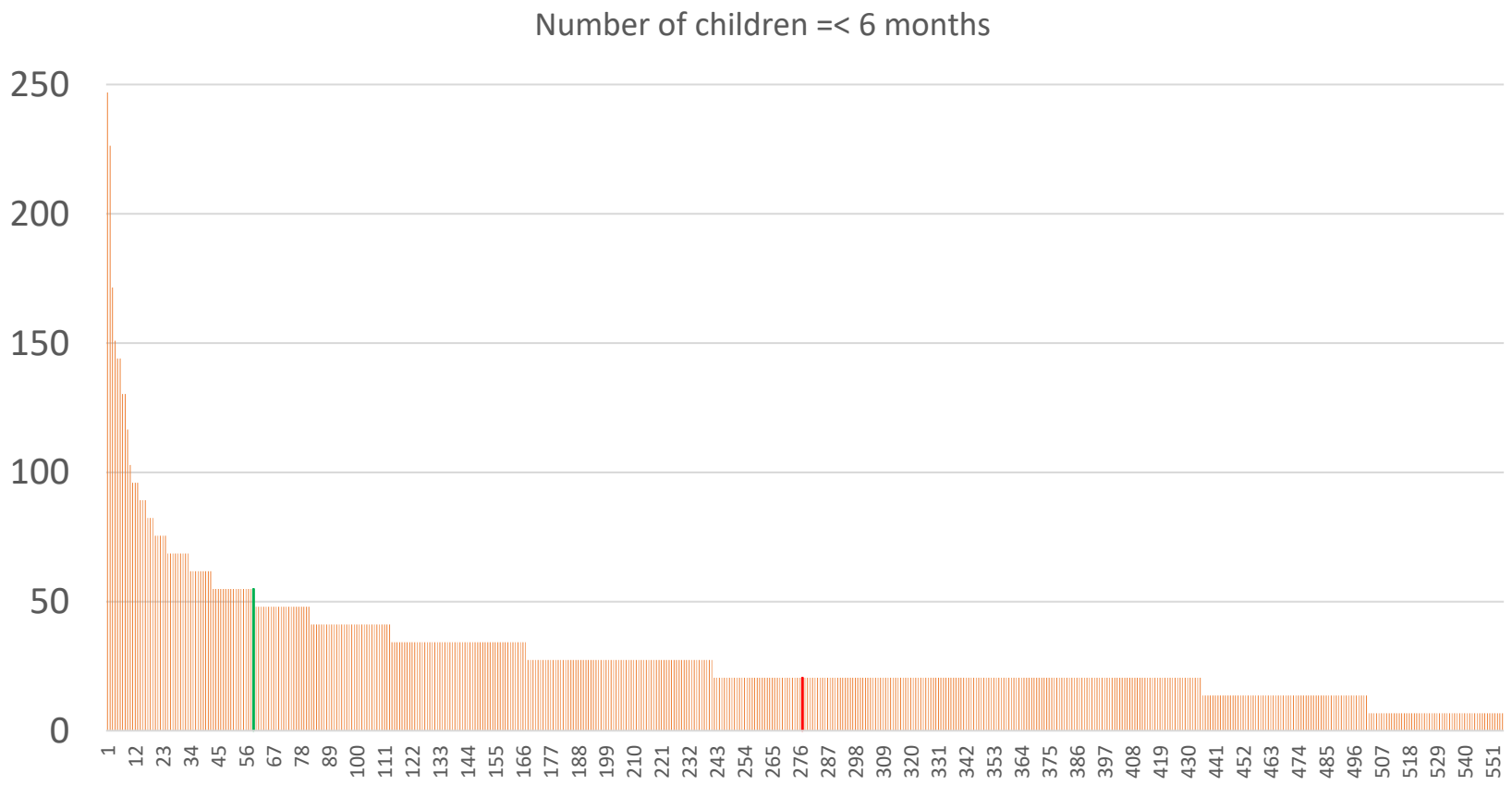
c) Paeds specialists – select small group of medically high-risk children entering their second RSV season

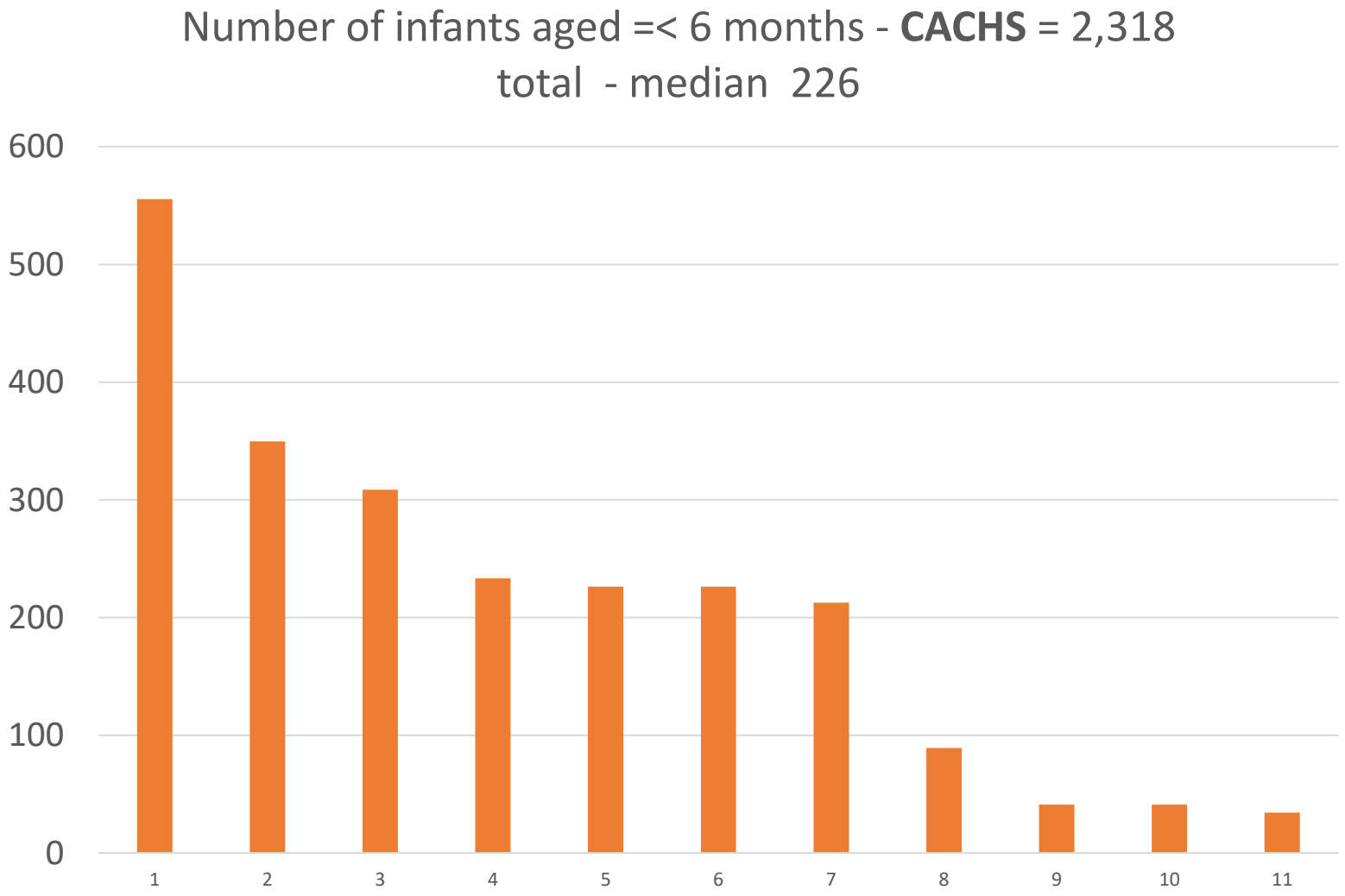
Nirsevimab Administration Issues

Pre-allocation strategy across 555 GPs

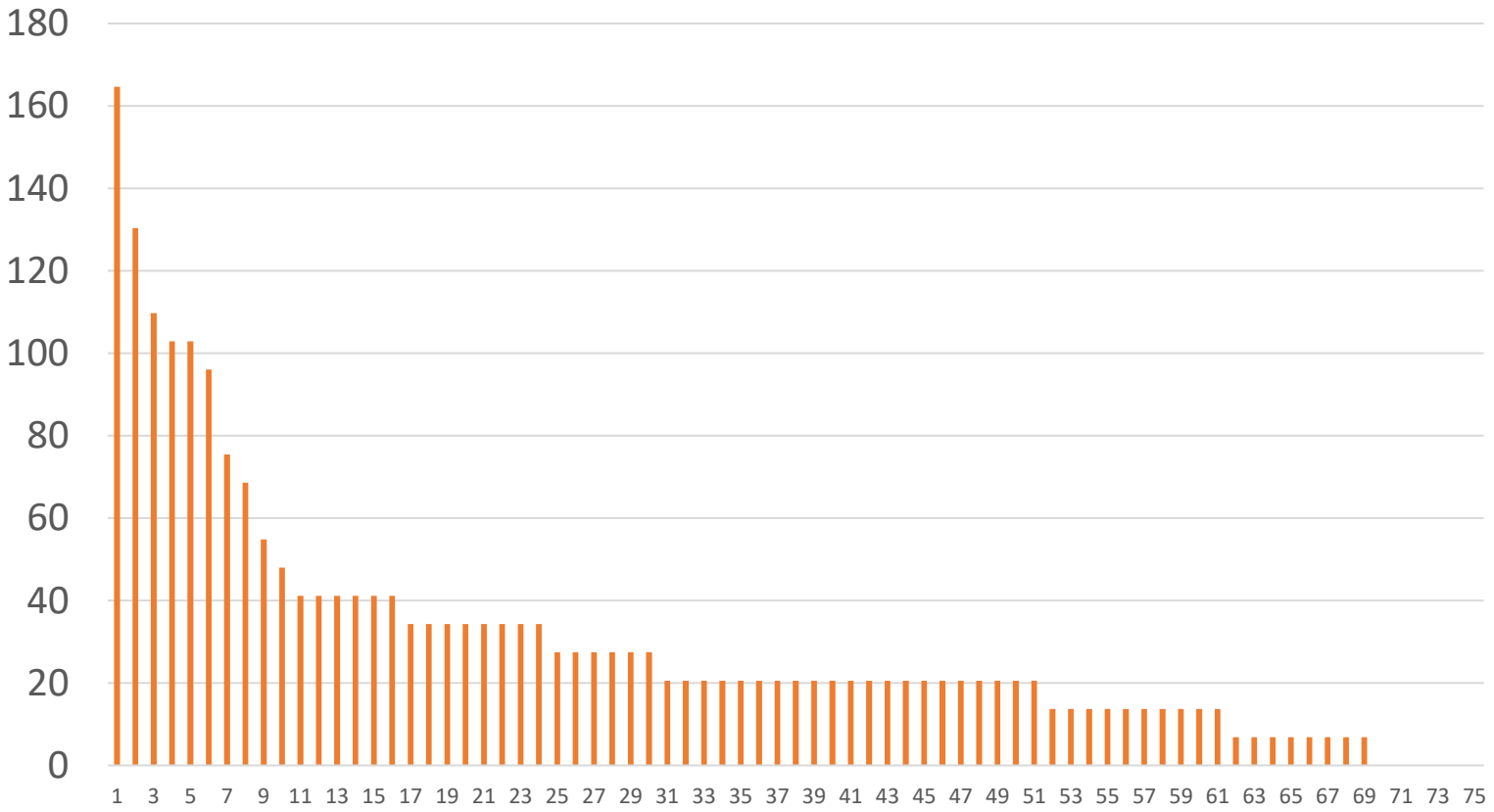
- Hexa/Vaxelis doses in 1 year/3 = approximate number of children =< 6months of age at a given practice

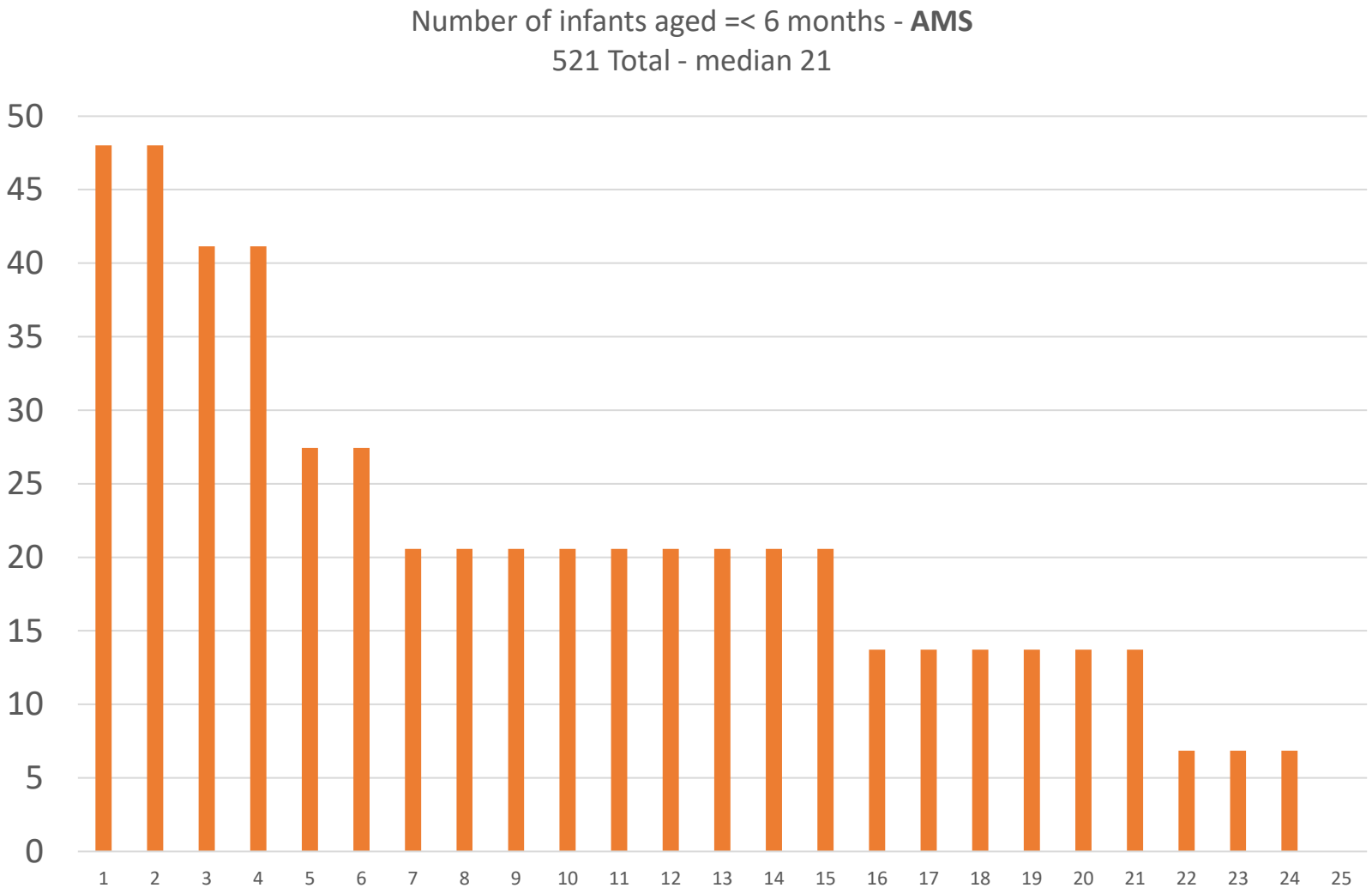
GP Practices
Total =16,371 Median is 29. Range of 7 – 247 children .




Number of infants aged =< 6 months - **CACHS** = 2,318 total - median 226
600
500
400
300
200
100
0
1
2
3
4
5
6
7
8
9
10
11

Number of infants aged =< 6 months - **WACHs** = 2,263
Total - median 21




Number of infants aged =< 6 months - **AMS**
521 Total - median 21
50
45
40
35
30
25
20
15
10
5
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25

Nirsevimab Administration Issues

- It is both scarce and expensive. Can't afford to have mal-distribution or wastage.
- Throughput.

Do Australian Parents know about RSV disease?

ACTA PÆDIATRICA
NURTURING THE CHILD

ORIGINAL ARTICLE

Parental awareness and attitudes towards prevention of respiratory syncytial virus in infants and young children in Australia

Charlie Holland ✉, Megan Baker, Amber Bates, Catherine Hughes, Peter C. Richmond, Samantha Carlson, Hannah C. Moore

First published: 01 February 2024 | https://doi.org/10.1111/apa.17127

Do Australian Parents know about RSV disease?

- Of the 1,992 participants in the national online survey, 89.6% of current parents and 78.7% of pregnant and planning parents knew about RSV.

- *Future* and *current* parents had **a high level of acceptance towards an infant RSV immunisation** prior to information being provided (93.4% and 81.4%, respectively)

CDC Announces Shortage of Nirsevimab, Used for RSV

October 24, 2023
Julia Bonavitacola

News *Article*

Nirsevimab, a monoclonal antibody used to protect infants from respiratory syncytial virus (RSV), is in limited supply, according to a CDC announcement.

The CDC announced on Monday, October 23, 2023, that there is a limited supply of nirsevimab, a monoclonal antibody that is recommended for use in infants to prevent lower respiratory tract disease associated with respiratory syncytial virus (RSV).

RSV is the most common cause of respiratory infection in the United States, primarily in infants within the first year of their life. The FDA approved nirsevimab, also known as Beyfortus, in July 2023 to give infants passive immunization against lower respiratory tract infections brought on by RSV. The CDC Advisory Committee on Immunization Practices (ACIP) recommended the antibody for infants younger than 8 months during or entering their first season of RSV, as well as infants aged 8 to 19 months who were at risk for severe RSV. RSV transmission is expected to increase nationwide within the next 1 to 2 months.

apm news

DISPATCH - Thursday, 08 February 2024 - 4:58 p.m.

Bronchiolite: first real -life French data confirm the efficacy of Beyfortus*

Keywords: #public health #infectio #health facilities #pediatrics #epidemio

INFECTIO

POLSAN - INSTITUTIONS

PARIS, February 8, 2024 (APMnews) - The data collected during the 2023-2024 winter season in France "appear to be consistent with a relatively high efficacy" of nirsevimab (Beyfortus*, Sanofi/AstraZeneca) to prevent hospitalizations for bronchiolitis in infants, at a level "probably quite close to what was published in randomized trials", was learned Thursday at a press briefing organized by the ANRS-Emerging Infectious Diseases (ANRS-MIE).

While the peak of the bronchiolitis epidemic was reached in the metropolis at the end of November 2023 (seefishing from 13/12/2023 to 18:53) and that the circulation of respiratory syncytial virus (RSV) is now "much less intense", with about "2% to 2,5% positivity among the samples taken in outpatient or in hospitalization", “This is an opportune time to look at what happened compared to previous years and learn some lessons about the impact of Nirsevimab.” stressed Prof. Naïm Ouldali, pediatrician in the Department of General Pediatrics at the Robert-Debré Hospital in Paris (AP-HP), during this press briefing devoted to respiratory virosis.

“The health authorities had estimated the number of doses to be ordered on the basis of an acceptance rate of 50% on the part of the parents, but "very quickly, we realized that these figures were very much below reality", noted the pediatrician.

In reality, "the vast majority of parents who were offered this antibody accepted it" and the **acceptability was finally "very high", "about 90%”.**

“The 200,000 doses initially ordered were therefore supplemented by 50,000 additional doses.”

“He also indicated that the **first safety data were "very reassuring",** "with for the moment side effects both infrequent and non-severe", and "no signal" pharmacovigilance.”

Talking with parents about RSV and Nirsevimab*

- More than half of all infants in WA will get infected by RSV this winter.
- While most infant's RSV illness will not be serious, it's impossible to predict which children will become severely ill.
- In WA, our hospital records show that 1 in every 25 children get hospitalised by RSV in their first year of life; most of these infants were previously healthy babies.
- Nirsevimab is a medicine that has been proven to be 80% effective at preventing RSV associated hospitalisation in infants.

* Effler's personal perspective

Talking with parents about RSV and Nirsevimab

- Nirsevimab is not a vaccine, but it does provide protective immunity because it contains antibodies that neutralise the RSV virus.

- Unlike a vaccine, the protection provided starts within hours after administration and is full strength within a few days.

- While nirsevimab is a recent RSV antibody medicine, we have been using other RSV antibody medicines to protect the most vulnerable babies for more than 20 years.

- Nirsevimab represents the ‘next generation’ of RSV antibody medicines – it works better and lasts longer.

Talking with parents about RSV and Nirsevimab

- In clinical trials, most children had no unwanted reactions to nirsevimab.
- Still, as with any medicine, there is always the very remote chance your baby could have serious allergic reaction.
- But more than a million doses of nirsevimab were administered to infants in the US and Europe last year and in my assessment the benefits clearly outweigh the potential risks.

Talking with providers about RSV and Nirsevimab

- We have a unique opportunity in WA to keep hundreds of infants from being hospitalised this winter
- But bringing nirsevimab into WA, in an of itself, will do nothing to protect these babies – we have to administer this preventive medicine to have impact
- That will take work
- But I think it will be worth the effort

Thank you!