

WA RSV Infant Immunisation Program

Public Health Update Immunisation Day

13 November 2024

Dr Paul Effler Senior Medical Advisor CDCD

health.wa.gov.au

Conflict of Interest Disclaimer

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

Outline

- RSV in infants
- What is nirsevimab
- How the WA program came to be
- Program development
- Uptake
- Safety
- Effectiveness/impact

Outline

RSV in infants

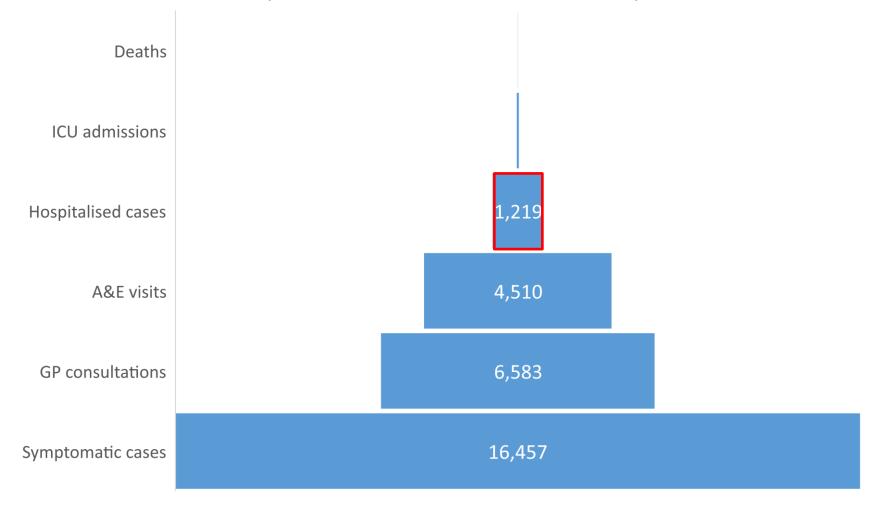
- What is nirsevimab
- How the WA program came to be
- Program development
- Optake
- Safety
- Effectiveness/impact

RSV Epidemiology

- RSV is the leading cause of infant hospitalisation in Australia.
- 55-65% of all infants are infected in the first year of life.
- In WA, approximately 1 in every 25 infants are hospitalised with RSV each year.



WA RSV infant burden of illness pyramid (benchmarked off UK data)



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

"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."

Outline

RSV in infants

What is nirsevimab

- How the WA program came to be
- Program development
- Optake

Safety

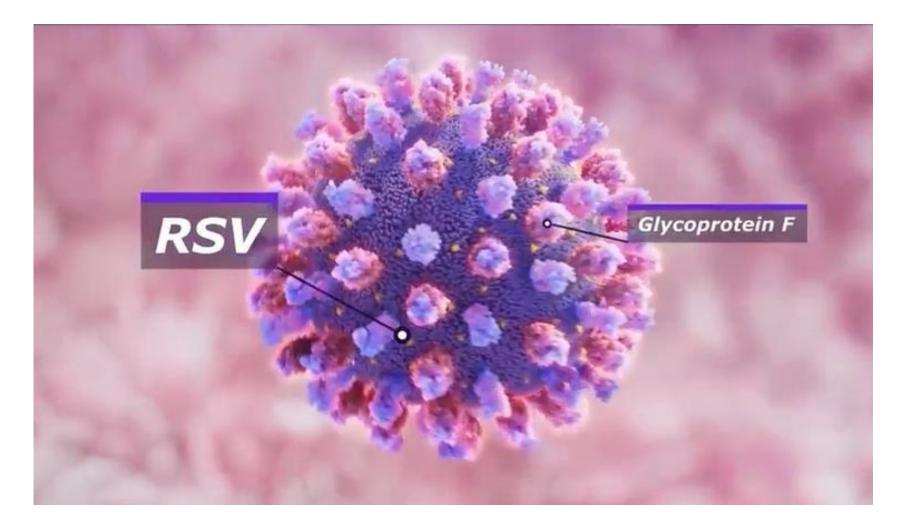
Effectiveness/impact

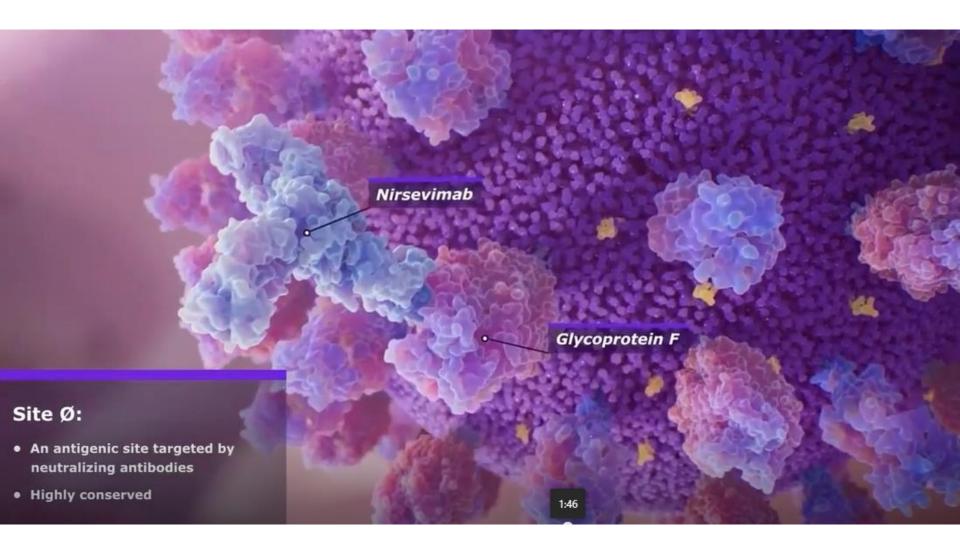
Nirsevimab (Beyfortus)

- 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)

Nirsevimab (Beyfortus)







Nirsevimab (Beyfortus)

In clinical trials Nirsevimab was shown to be:

- 77% effective at preventing RSV-associated LRTI with hospitalisation
- 90% effective at preventing RSV-associated LRTI with ICU admission.

Outline

- RSV in infants
- What is nirsevimab
- How the WA program came to be
- Program development
- Optake
- Safety
- Effectiveness/impact

- July 2023 meeting with Sanofi
- August 2023 MfH requests review of data
- Spring 2023 'Nirsevimab is not a vaccine'...
- October 2023 Consulted with WA paeds docs



Dr Peter Richmond



Dr Asha Bowen



Dr Chris Blyth

"Game changer for paediatrics"

Outline

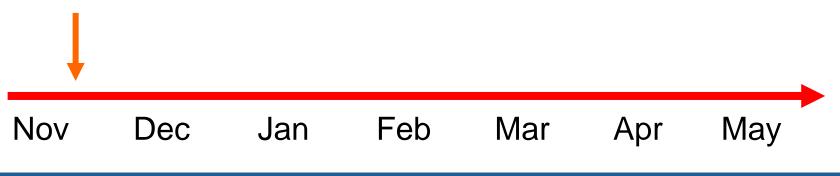
- RSV in infants
- What is nirsevimab
- How the WA program came to be
- Program development
- Optake
- Safety
- Effectiveness/impact

Nirsevimab registration

On 24 November TGA registered Nirsevimab.

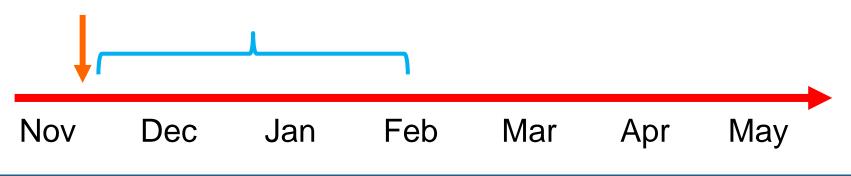
The indication is:

- 1. Infants entering 1st RSV season
- 2. High-risk children entering 2nd RSV season



Over the next 3 months DOH designed the state-wide rollout:

- prepared an urgent submission to the Expenditure Review Committee to request funding
- negotiated costs with the manufacturer
- consulted Paeds ID clinicians and others to determine eligibility criteria
- calculated doses needed and dosage splits
- engaged with GPs, midwives, AMSs and others on the implementation strategy



WA Nirsevimab Eligibility

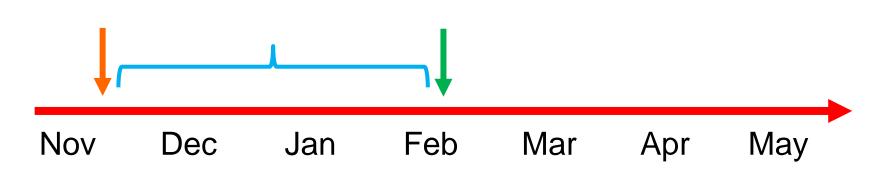
Four-target cohorts:

- 1. All infants born on or after 1 Oct 2023 (catch-up cohort entering first RSV season)
- 2. All infants born during RSV season (1 May- 30 Sep)
- 3. Children with specific medical risk conditions entering their second RSV season
- 4. All Aboriginal children entering their second RSV season

Hospital ICD discharge codes for RSV disease by year, year of age, and Aboriginality, WA

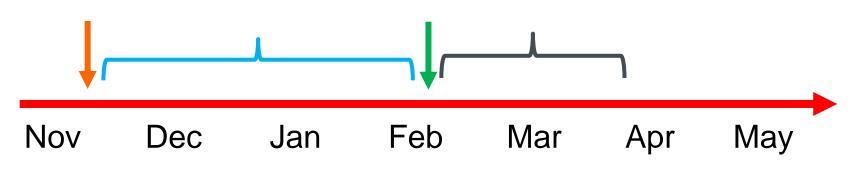
| | | | Aboriginal | | | Non-Aboriginal | | | |
|------|------------------|-------|--------------|--------------------|---|----------------|--------------|--------------------|--|
| | | Pop. | RSV Hosp. | Rate per 10,000 | | Pop. | RSV Hosp. | Rate per 10,000 | |
| 2022 | Under 1 year | 1,997 | 224 | 1122 | | 31,027 | 1127 | 363 | |
| | 1 to less than 2 | 2,032 | 65 | 320 |] | 30,763 | 333 | 108 | |
| 2023 | Under 1 year | 1,997 | 286 | 1432 | | 31,027 | 1093 | 352 | |
| | 1 to less than 2 | 2,032 | 72 | 354 |] | 30,763 | 311 | 101 | |

Funding for the Program (\$11 million) was approved on 19 February 2024



Six-week scramble:

- procured and began distribution of 27,000-plus doses to 690 clinical sites
- lobbied for nirsevimab to be included on AIR
- developed written directions to permit community nurses to administer nirsevimab
- arranged for additional public immunisation clinics
- developed a training course for clinicians
- conducted multiple webinars/seminars for various stakeholders
- created numerous program support materials





Respiratory Syncytial Virus (RSV) infant immunisation program

Fact sheet – for providers

What is RSV?

RSV, or <u>Respiratory Syncytial Virus</u>, causes illness in people of all ages, but infants aged less than 6 months are at a higher risk of severe disease.

RSV infections are often mild with symptoms similar to a common cold. RSV is one of the most frequent causes of coughs, colds and earaches. However, patients with RSV may also deteriorate rapidly, resulting in:

- bronchiolitis (chest infection)
- pneumonia (lung infection)
- croup (voice box and windpipe infection).

Globally, deaths due to RSV are 5-times higher than deaths from influenza among children under 1 year.

Why is an RSV infant immunisation program being introduced in WA?

infant immunisation program this year. This time-limited program will run from early April to 30 September 2024.

Please note that Beyfortus® is currently not on the Pharmaceutical Benefits Scheme or National Immunisation Program.

What is the difference between a monoclonal antibody and a vaccine?

A vaccine stimulates your immune system to mount a response, which includes making antibodies, a process referred to as 'active immunisation'. This process can take up to 2 weeks after you get vaccinated and may require more than one exposure to the antigen(s) in the vaccine.

In contrast, nirsevimab contains pre-formed antibodies against a protein on the surface of the RSV virus that can prevent the virus from entering cells. This 'passive immunisation' does not require an immune response



Nirsevimab – What parents need to know Consumer information sheet

What is Respiratory Syncytial Virus (RSV)?

RSV is a common respiratory virus that usually causes mild, cold-like symptoms but can also cause more serious illness.

Symptoms of RSV infection may include runny nose, decrease in appetite, coughing, sneezing, fever or wheezing.

RSV is easily spread, and most children will get an RSV infection by the time they are 2-years-old. While the majority will recover within a week or two, RSV infection can be dangerous for infants and young children, causing difficulty breathing, low oxygen levels and dehydration.

In Australia, RSV infection is the most common cause of infant hospitalisation because it can

Why should you immunise your baby with nirsevimab?

The antibody in nirsevimab can prevent severe lung disease caused by RSV. Medical studies show nirsevimab to be about 80 per cent effective at preventing RSV-associated hospitalisation among infants entering their first RSV season and 90 per cent effective at preventing an admission to an intensive care unit (ICU).

Who is eligible for nirsevimab?

The below 4 cohorts are eligible for nirsevimab immunisation under this program.

From 1 April 2024 to 30 September 2024, nirsevimab will be offered:



Nirsevimab – What Aboriginal parents need to know Consumer information sheet

What is RSV?

RSV is a highly contagious virus that can infect people of all ages. It can cause a range of respiratory illnesses from mild colds to severe conditions like bronchiolitis (inflammation of the small airways of the lungs), or pneumonia (lung infection). It mostly affects babies and young children but can also occur in older adults.

Symptoms of RSV can include:

- runny nose
- decrease in appetite
- coughing
- sneezing
- fever
- wheezing and difficulty breathing (including worsening of asthma).

Who is eligible for nirsevimab?

The below 4 cohorts are eligible for nirsevimab immunisation under this program.

From 1 April 2024 to 30 September 2024, nirsevimab will be offered:

- as a catch-up program for babies born from 1 October 2023 to 30 April 2024
- to all Aboriginal children born from 1 October 2022 to 30 September 2024
- to some medically at-risk children in their second RSV season born from 1 October 2022 to 30 September 2023 (Your child's doctor will advise you if your child should receive a dose before their second RSV season).

In addition:





WA RSV Infant Immunisation Program: What expecting and new parents need to know

The WA Government is funding immunisation against Respiratory Syncytial Virus (RSV) for all babies born in WA between 1 May and September 2024. This fact sheet provides important information about RSV illness in infants and the RSV immunisation medicine.

What is RSV?

RSV is a highly contagious virus that infects the upper airway and lungs. More than half of all infants will become infected in their first year of life. While most children will recover from their illness within several weeks, RSV infection can be life-threatening for some infants. It's impossible to predict which infants will become severely ill because most children hospitalised with RSV were previously healthy.

Is nirsevimab considered a vaccine?

No, it is an immunisation medicine. A vaccine is a substance that triggers a person's immune system to make protective antibodies against a specific germ. In contrast, nirsevimab provides pre-made protective antibodies directly to the recipient. Immunisation medicines containing protective antibodies against other serious diseases have been available for many years (e.g. tetanus, hepatitis and rabies).

How does nirsevimab work?

When a baby is exposed to the RSV virus, the antibody in nirsevimab attaches tightly to the virus's surface, preventing it from reproducing and greatly reducing its ability to cause illness.

What parents need to know - factsheets and translated information

Translated Version

- Nirsevimab what parents need to know (Arabic) (PDF 1.14 MB)
- Nirsevimab what parents need to know (Burmese) (PDF 1.21 MB)
- Nirsevimab what parents need to know (DARI) (PDF 1.13 MB)
- Nirsevimab what parents need to know (Hindi) (PDF 1.18MB)
- Nirsevimab what parents need to know (Korean) (PDF 1.24 MB)
- Nirsevimab what parents need to know (Karen) (PDF 1.20 MB)
- Nirsevimab what parents need to know (Thai) (PDF 1.17 MB)
- Nirsevimab what parents need to know (Vietnamese) (PDF 1.16 MB)
- Nirsevimab what parents need to know (Simple Chinese) (PDF 1.34 MB)



니르세비맙(Nirsevimab) – 부모님께서 알아두셔야 할 사항 소비자 정보 안내

호흡기세포융합바이러스란(RSV)란 무엇인가요?

RSV는 일반적으로 경미하고 감기와 같은 증상을 유발하지만 더 심각한 질병을 유발할 수도 있는 일반적인 호흡기 바이러스입니다.

RSV 감염의 증상에는 콧물, 식욕 감소, 기침, 재채기, 발열 또는 천명음이 있을 수 있습니다.

RSV는 쉽게 전파되며 대부분의 영유아가 2세가 될 때까지 RSV에 감염됩니다. 대다수는 1~2주 내에 회복되지만, RSV 감염은 영유아에게 위험할 수 있으며 호흡 곤란, 낮은 산소 수치 및 탈수를 유발할 수 있습니다.

호주에서는 RSV 감염이 영유아 입원의 가장 흔한 원인입니다. 왜냐하면 RSV 감염은 매우 어린 영유아에서 종종 폐렴(폐 감염) 또는 세기관지염 (폐의 작은 기도 염증)으로 진행될 수 있기 때문입니다. 매년 서호주(WA)에서는 겨울철 질병 기간 동안 영유아 30명 중 1명이 RSV로 입원합니다.

니르세비맙(Nisevimab)이란 무엇입니까?

왜 아기에게 니르세비맙(nirsevimab)을 접종해야 합니까?

니르세비맙(nirsevimab)의 항체는 RSV로 인한 심각한 폐 질환을 예방할 수 있습니다. 의학 연구에 따르면 니르세비맙은 첫 번째 RSV 시즌에 들어가는 유아의 RSV 관련 입원을 예방하는 데 약 80% 효과적이며 중환자실(ICU) 입원을 예방하는 데 90% 효과적인 것으로 나타났습니다.

니르세비맙(Nirsevimab) 예방접종 자격이 있는 사람은 누구입니까?

아래 4개 군에 소속된 영유아는 이 프로그램에 따라 니르세비맙(nirsevimab) 예방접종을 받을 자격이 있습니다.

2024년 4월 1일부터 2024년 9월 30일까지 니르세비맙(nirsevimab)이 제공됩니다.

- 2023년 10월 1일부터 2024년 4월 30일 사이에 태어난 영유아는 캐치업 프로그램으로 예방접종 가능
- 2022년 10월 1일부터 2024년 9월 30일 사이에 태어난 모든 원주민 영유아

WA Nirsevimab Training Module



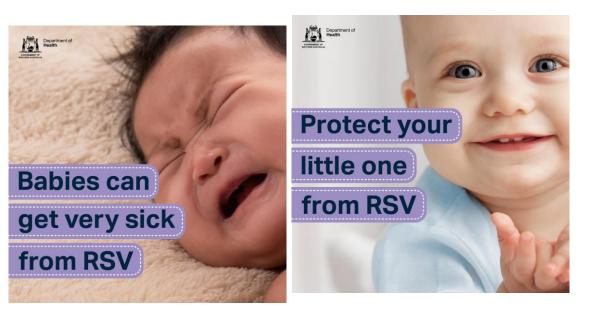


Introduction

Welcome to the Western Australia (WA) RSV Infant Immunisation Program online training module. This module will provide you with the information necessary to competently administer nirsevimab, a monoclonal antibody medicine that can prevent severe RSV illness among young infants. Successfully completing this module will satisfy your obligation to undertake specific training regarding the RSV Infant Immunisation Program in order to be compliant with requirements of the Structured Administration and Supply Arrangements (SASA) authorising the administration of nirsevimab in WA.













https://www.health.wa.gov.au/Articles/A_E/Campaign-RSV

health.wa.gov.au



Government of Western Australia Department of Health

Respiratory Syncytial Virus (RSV)

Affix unique patient identification label in this box

Please print clearly in capital letters using a blue or black ball point pen.

Infant's details

| First name (if known) | | | | | | | | | | |
|--|----------|-----------------|----------------------------|--|--|--|--|--|--|--|
| Note: Where the baby has not been named, use the term 'Baby of' as the first name. For a multiple birth, use 'Baby 1 of', 'Baby 2 of'. | | | | | | | | | | |
| Last name (use mother's surname) | | | | | | | | | | |
| Date of birth (DD/MM/YYYY)/ | | | | | | | | | | |
| Sex: Male O | Female O | Indeterminate O | Medicare number (if known) | | | | | | | |

Parent or guardian's details

| Person providing consent (select one): Mother O Father O Other (specify) | | | | | |
|---|--|--|--|--|--|
| ame Last name | | | | | |
| Telephone number (mobile preferred) | | | | | |
| Mother's address: same address as the mother's Medicare records. | | | | | |
| | | | | | |
| Postcode | | | | | |
| Mother's address is required to record infant's immunisation in the Australian Immunisation Register. | | | | | |

Consent to administer nirsevimab (Beyfortus®)

I have read and understood the information contained in the Nirsevimab – What parents need to know information sheet regarding the potential benefits and risks of nirsevimab.

Yes O No O

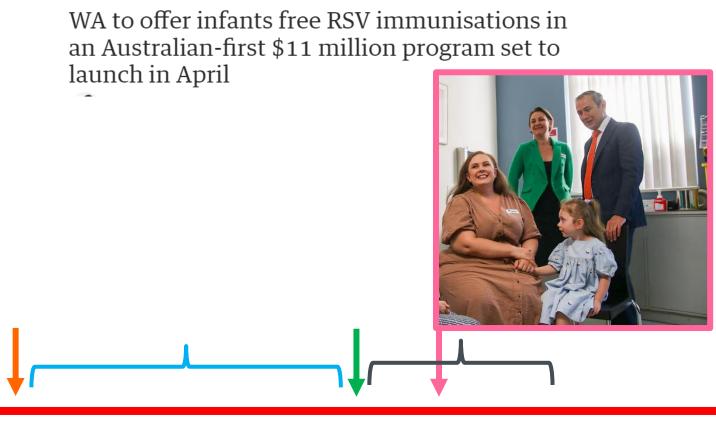
The Program announced by the Premier and the Minister for Health on 5 March.

The Mest Anstralian

Jan

a EXCLUSIVE

Dec



Feb

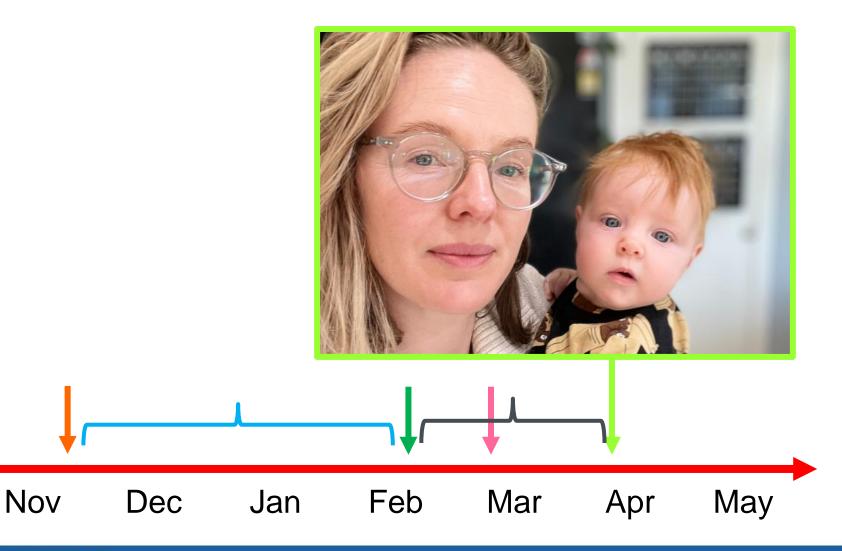
Mar

Nov

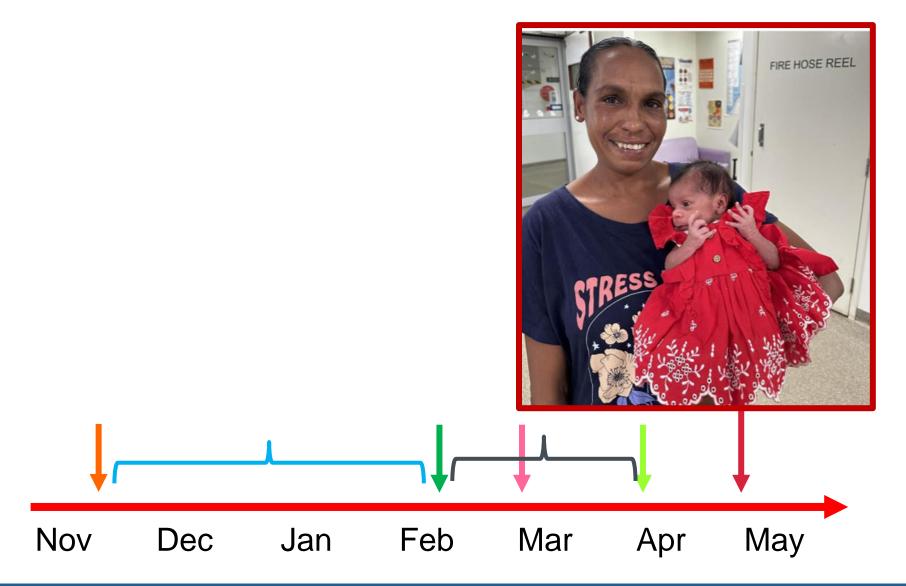
May

Apr

Catch-up program began 2 April



Birth hospital program began 1 May



Letter sent by the CHO to all mothers of babies born in WA from 1 Oct 2023.



Government of Western Australia Department of Health

<first name and surname> <First line address> <Suburb> <Postcode>

Dear Ms. <Last name>

RE: PROTECTING YOUR NEW BABY FROM SERIOUS ILLNESS CAUSED BY RSV

I am pleased to inform you that your newborn may be eligible to be immunised against serious illness caused by Respiratory Syncytial Virus (RSV) through the Western Australia (WA) RSV Infant Immunisation Program.

RSV is easily spread, and most babies will get infected by the virus during their first year of life. While many babies will recover from their illness within a week or two, RSV infection can be serious. In fact, RSV the most common cause of infant hospitalisation in Australia and each winter more than 1,000 infants in WA are hospitalised due to RSV. RSV infection early in life can also lead to longer term health issues, such as childhood asthma.

Fortunately, a new medicine, called Beyfortus®/nirsevimab, has proven to be highly effective at protecting infants from severe RSV illness. Medical studies and real-world experience show Beyfortus® is about 80 per cent effective at preventing RSV-associated infant hospitalisations and 90 per cent effective at preventing an admission to an intensive care unit (ICU).

Beyfortus® is not a vaccine, but rather a medicine that contains antibodies which prevent the RSV virus from spreading within the body. Like a vaccine, Beyfortus® is administered by injection and can be given at the same visit with other childhood immunisations.

The WA Government is funding this preventive immunisation for all children born between 1 October 2023 and 30 September 2024.

If your newborn was given Beyfortus® before being discharged from the hospital, they're all set and don't need any more doses. If you are unsure about whether your newborn was given Beyfortus® before leaving the hospital, check to see if it was recorded in your child's "Purple Book". If you are still unsure if your new baby has been immunised against RSV you should discuss with your child's health care provider.

> 189 Royal Street East Perth Western Australia 8004 Telephone (08) 9222 222 TTV 133 677 PO Box 8172 Perth Business Centre Western Australia 6849 ABN 28 684 750 332 www.heality.wa.gov.au

2

If your newborn was not immunised against RSV before leaving the hospital or was home birthed, it's not too late to get them protected. Beyfortus® is available through General Practice, Community Health Clinics and Aboriginal Medical Services throughout WA. Since WA's RSV season is already underway, I urge you to contact your preferred immunisation provider to discuss with them.

Your child's immunisation provider can tell you more about RSV illness and Beyfortus®. Information about the WA RSV Infant Immunisation Program, including a fact sheet called "What parents need to know", is also available on the WA Department of Health website at https://www.health.wa.gov.au/Articles/N_R/Respiratory-syncytial-virus-RSV-immunisation

Yours sincerely

Dr Paul Armstrong A/CHIEF HEALTH OFFICER A/ASSISTANT DIRECTOR GENERAL PUBLIC AND ABORIGINAL HEALTH DIVISION

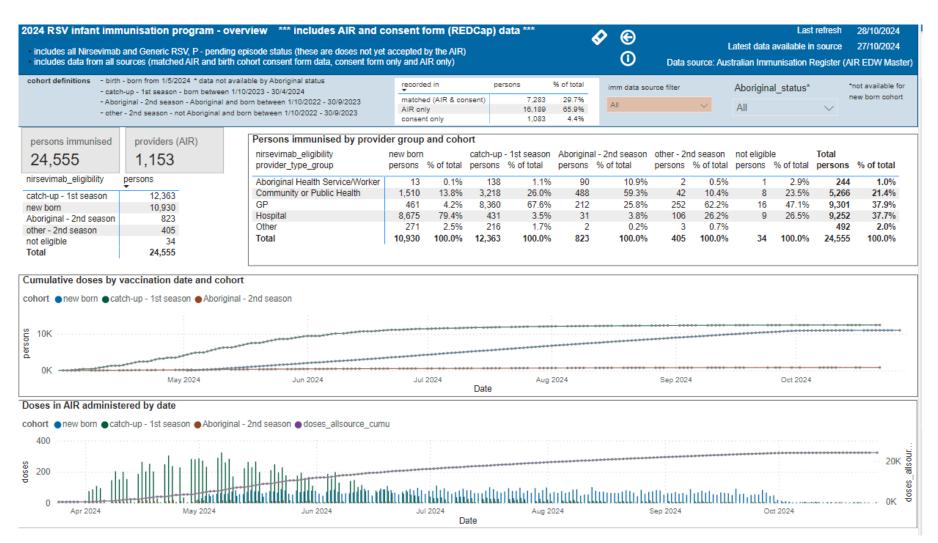
23 May 2024

GOVERNMENT OF WESTERN AUSTRALIA

Outline

- RSV in infants
- What is nirsevimab
- How the WA program came to be
- Program development
- Uptake
- Safety
- Effectiveness/impact

WA Nirsevimab Administration Dashboard



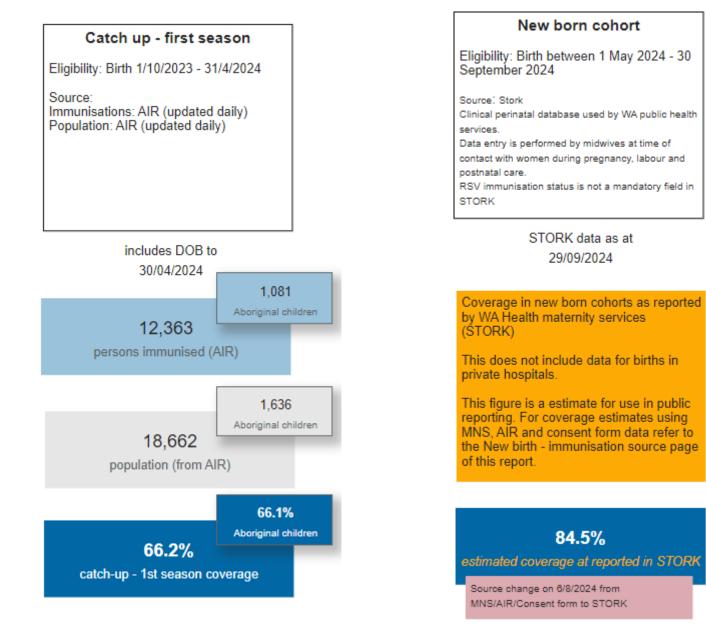
High level outcomes

| persons immunised | providers (AIR) |
|-------------------|-----------------|
| 24,555 | 1,153 |

| nirsevimab_eligibility | persons T | |
|-------------------------|--------------|--|
| catch-up - 1st season | 12,363 | |
| new born | 10,930 | |
| Aboriginal - 2nd season | 823 | |
| other - 2nd season | 405 | |

Persons immunised with Nirsevimab by provider type WA 2024

- General practitioners 9,319 (37.8%)
- Hospital (midwives/nurses) 9,316 (37.8%)
- Community Health Nurses 5,254 (21.3%)
- Aboriginal Health Service 245 (1.0%)
- Other 492 (2.0%)



Catch-up 66%

Newborns ~ 80-85%

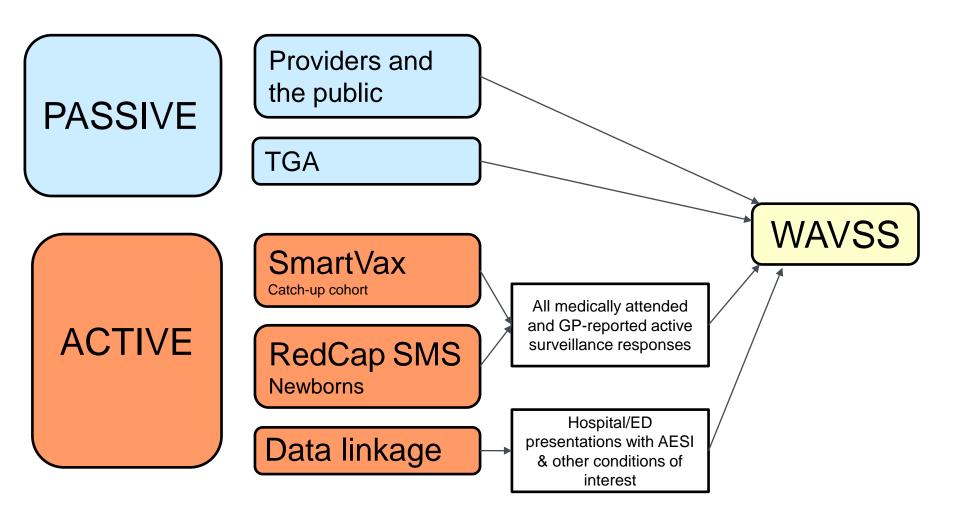
Outline

- RSV in infants
- What is nirsevimab
- How the WA program came to be
- Program development
- Optake

Safety

Effectiveness/impact

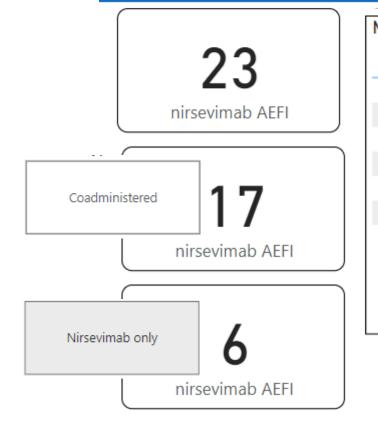
WA nirsevimab safety surveillance



WAVSS

WAVSS safety summary - infants

Latest available data: 1/09/2024



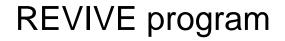
| Most commonly reported reactions (nirsevimab) | | | |
|--|-------------------|--|--|
| Reaction | Number of reports | | |
| Rash | 6 | | |
| Irritability | 5 | | |
| Lethargy | 5 | | |
| Vomiting | 5 | | |
| Fever (>=38 <40°C) | 4 | | |
| Fever (unspecified) | 4 | | |
| Injection site reaction - minor/common/expected | 4 | | |
| | | | |
| | | | |

Outline

- RSV in infants
- What is nirsevimab
- How the WA program came to be
- Program development
- Optake

Safety

Effectiveness/Impact





Perth Children's Hospital Foundation

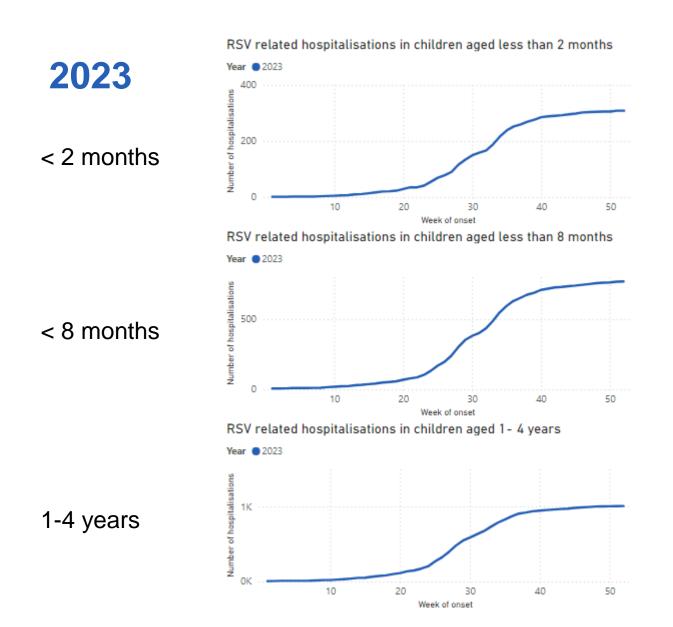
Test Negative Control Case Control study

Nirsevimab Effectiveness = ?%



Dr Ushma Wadia





health.wa.gov.au



Lab test positive RSV hospitalisations by year and age group, WA

| WA RSV associated hospitalisations | | | | |
|------------------------------------|------|------|-----------|--|
| | | | 2022-2023 | |
| Year of age | 2022 | 2023 | mean | |
| 0-<1 | 938 | 993 | 965.5 | |
| 1-<2 | 501 | 580 | 540.5 | |
| 2-<3 | 221 | 218 | 219.5 | |
| 3-<4 | 116 | 104 | 110 | |
| 4-<5 | 56 | 81 | 68.5 | |

At \$13,695 per infant hospitalisation that's \$7.2 million in savings The cost for nirsveimab doses for < 1 year olds was \$7.6 million

RSV Infant Immunisation Impact in Primary Care?



Dr Ramya Raman RACGP Western Australia Faculty Chair

"We all got to have lunch this winter."

WA RSV Infant Immunisation Program Summary

- It was a lot of work
- Many partners came through for us
- Uptake was very good
- Acceptable safety profile
- Nirsevimab effectiveness was just like the RCTs
- The impact was impressive
- The effort was worth it



Virus killer baby joy

Free RSV vaccinations hailed huge success by doctors

REBECCA PARISH

Fewer babies were admitted to hospital with RSV this year due to the success of free vaccinations in WA.

Hospital admissions were almost 84 per cent down on anticipated numbers as a result. More than 23,000 children

were vaccinated between April and September, with free jabs offered to newborns, infants up to eight months and vulnerable toddlers.

"In previous years, we would see young child after young child with RSV admitted to hospital in the middle of the winter season," Perth Children's Hospital clinician Chris Blyth said. "It would significantly impact on our emergency department with baby after baby coming in with this significant illness.

"We saw significantly less of that this year ... Our RSV and our flu season coincided this year, so if we hadn't got this program it would have meant managing the hospital would have been incredibly hard."

Professor Blyth, who was also key investigator for a study of the program's effectiveness, said about 1000 RSV-related hospital admissions were recorded in children aged under two in WA each year.

Infants under six months were most at risk from the potentially deadly virus.

Mundaring mum Shenay Jones said discussions about vaccinating her baby started

when she was 36 weeks pregnant. It was a "no-brainier" for her after seeing other children become very unwell from the condition.

Her third child, four-monthold daughter Lilah, was vaccinated a few hours after birth and Ms Jones said she was a "very healthy" baby. "It was definitely important

to me to protect her as much as I could," Ms Jones said. "I think it's amazing we live

I think it's amazing we live in a country (with) these options to immunise our babies and protect them, especially from something nasty like RSV where they can end up in hospital, quite unwell."

Perth-based Immunisation Foundation of Australia founder and director Catherine

Hughes said the results would hopefully ensure the program was repeated in future years and that "all babies, in all postcodes" were protected.

"These results show the remarkable difference RSV protection has made, not only to the lives of families but also to the immense burden faced by our health services every winter," she said.

"By slashing the annual number of RSV hospitalisations by 60 per cent, this program has alleviated the pressure on hospitals during peak respiratory season, freeing up beds and easing workload pressures."

WA's free RSV vaccines program was the first in the southern hemisphere.

Acknowledgement of Partners

- Aboriginal Health Council of Western Australia
- Australian College of Midwives (ACM)
- Child and Adolescent Health Service (CAHS)
- DOH Immunisation Program
- DOH Information & Performance Governance Unit
- DOH Surveillance and Disease Control Program
- Immunisation Foundation Australia (IFA)
- RACGP(WA)
- RANZCOG(WA)
- WA Country Health Service (WACHS)
- WA Health Chief Nursing and Midwifery Office
- WA Health Communications and Engagement
- WA Primary Health Alliance (WAPHA)



Dr Rosanna Capolingua



Thank you!