



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

WA 2025 Expanded RSV Infant and Maternal Immunisation Program

23 January 2025

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CDCD

Conflict of Interest Disclaimer

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

RSV Infant Immunisations

Outline of this session

- What WA achieved in 2024
- Looking forward to 2025
- Abrysvo – the new kid on the block
- Beyfortus/nirsevimab review
- Putting it all together

WA 2024 RSV Infant Immunisation Program

Four cohorts eligible for Beyfortus:

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

WA 2024 RSV Infant Immunisation Program

How did it go?

1. Coverage
2. Safety
3. Effectiveness
4. Impact

WA 2024 RSV Infant Immunisation Program

How did it go?

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WA Nirsevimab Administration Dashboard

2024 RSV infant immunisation program - overview *** includes AIR and consent form (REDCap) data ***

- includes all Nirsevimab and Generic RSV, P - pending episode status (these are doses not yet accepted by the AIR)
- includes data from all sources (matched AIR and birth cohort consent form data, consent form only and AIR only)

Last refresh 28/10/2024

Latest data available in source 27/10/2024

Data source: Australian Immunisation Register (AIR EDW Master)

cohort definitions

- birth - born from 1/5/2024 * data not available by Aboriginal status
- catch-up - 1st season - born between 1/10/2023 - 30/4/2024
- Aboriginal - 2nd season - Aboriginal and born between 1/10/2022 - 30/9/2023
- other - 2nd season - not Aboriginal and born between 1/10/2022 - 30/9/2023

| recorded in | persons | % of total |
|-------------------------|---------|------------|
| matched (AIR & consent) | 7,283 | 29.7% |
| AIR only | 16,189 | 65.9% |
| consent only | 1,083 | 4.4% |

imm data source filter

All

Aboriginal_status*

All

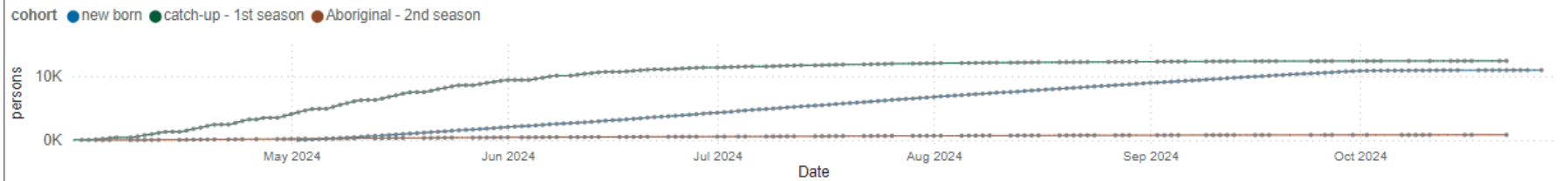
*not available for new born cohort

| | |
|-------------------------|---------------|
| persons immunised | 24,555 |
| providers (AIR) | 1,153 |
| nirsevimab_eligibility | persons |
| catch-up - 1st season | 12,363 |
| new born | 10,930 |
| Aboriginal - 2nd season | 823 |
| other - 2nd season | 405 |
| not eligible | 34 |
| Total | 24,555 |

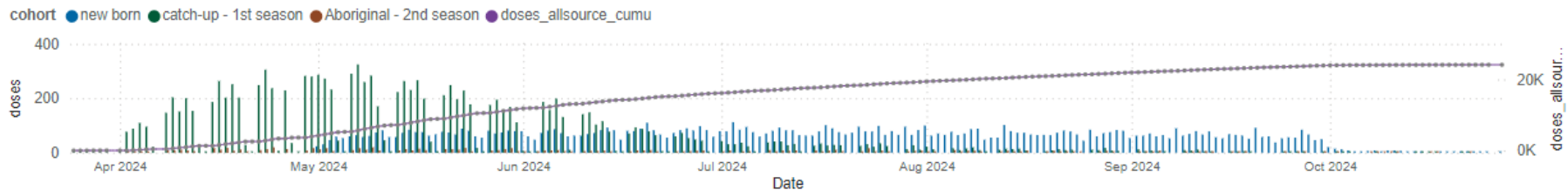
Persons immunised by provider group and cohort

| nirsevimab_eligibility provider_type_group | new born | | catch-up - 1st season | | Aboriginal - 2nd season | | other - 2nd season | | not eligible | | Total | |
|---|---------------|---------------|-----------------------|---------------|-------------------------|---------------|--------------------|---------------|--------------|---------------|---------------|---------------|
| | persons | % of total | persons | % of total | persons | % of total | persons | % of total | persons | % of total | persons | % of total |
| Aboriginal Health Service/Worker | 13 | 0.1% | 138 | 1.1% | 90 | 10.9% | 2 | 0.5% | 1 | 2.9% | 244 | 1.0% |
| Community or Public Health | 1,510 | 13.8% | 3,218 | 26.0% | 488 | 59.3% | 42 | 10.4% | 8 | 23.5% | 5,266 | 21.4% |
| GP | 461 | 4.2% | 8,360 | 67.6% | 212 | 25.8% | 252 | 62.2% | 16 | 47.1% | 9,301 | 37.9% |
| Hospital | 8,675 | 79.4% | 431 | 3.5% | 31 | 3.8% | 106 | 26.2% | 9 | 26.5% | 9,252 | 37.7% |
| Other | 271 | 2.5% | 216 | 1.7% | 2 | 0.2% | 3 | 0.7% | | | 492 | 2.0% |
| Total | 10,930 | 100.0% | 12,363 | 100.0% | 823 | 100.0% | 405 | 100.0% | 34 | 100.0% | 24,555 | 100.0% |

Cumulative doses by vaccination date and cohort



Doses in AIR administered by date



High level outcomes

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

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

Persons immunised with Nirsevimab by provider type WA 2024

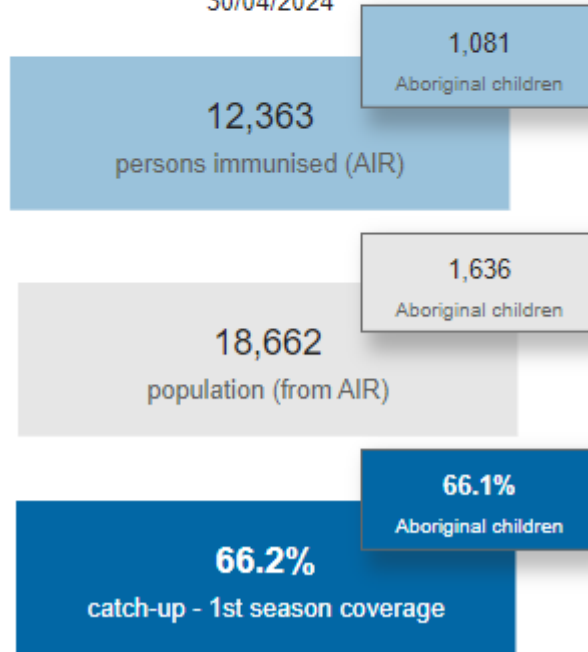
| | | |
|----------------------------|-------|---------|
| General practitioners | 9,309 | (37.9%) |
| Hospital (midwives/nurses) | 9,266 | (37.7%) |
| Community Health Nurses | 5,252 | (21.4%) |
| Aboriginal Health Service | 244 | (1.0%) |
| Other | 492 | (2.0%) |

Catch up - first season

Eligibility: Birth 1/10/2023 - 31/4/2024

Source:
Immunisations: AIR (updated daily)
Population: AIR (updated daily)

includes DOB to
30/04/2024



Catch-up 66%

New born cohort

Eligibility: Birth between 1 May 2024 - 30 September 2024

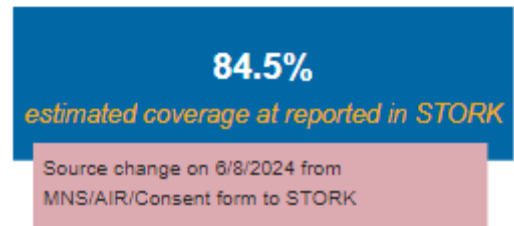
Source: Stork
Clinical perinatal database used by WA public health services.
Data entry is performed by midwives at time of contact with women during pregnancy, labour and postnatal care.
RSV immunisation status is not a mandatory field in STORK

STORK data as at
29/09/2024

Coverage in new born cohorts as reported by WA Health maternity services (STORK)

This does not include data for births in private hospitals.

This figure is a estimate for use in public reporting. For coverage estimates using MNS, AIR and consent form data refer to the New birth - immunisation source page of this report.



Newborns ~ 80%

WA 2024 RSV Infant Immunisation Program

How did it go?

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WA Vaccine Safety Surveillance

No serious
adverse events
identified

2024 RSV infant immunisation program

WAVSS safety summary - infants

25

nirsevimab AEFI

23,789

nirsevimab encounters

WAVSS baseline comparison*

| Encounter type | AEFI reports | Encounters | AEFI rate |
|----------------|--------------|------------|-----------|
| Baseline | 17 | 28,428 | 59.80 |

Most commonly reported reactions (nirsevimab)

| Reaction | Number of reports |
|--|-------------------|
| Rash | 6 |
| irritability | 5 |
| Lethargy | 5 |
| Vomiting | 5 |
| Fever ($\geq 38 < 40^{\circ}\text{C}$) | 4 |
| Fever (unspecified) | 4 |
| Injection site reaction - minor/common/expected | 4 |

WA 2024 RSV Infant Immunisation Program

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REVIVE program



Test Negative Control Case Control study

ARI Hospitalisation PCH and FSH

| | RSV positive | RSV negative |
|----------------|--------------|--------------|
| Nirsevimab Yes | 36 | 51 |
| Nirsevimab No | 109 | 30 |

Nirsevimab Effectiveness* = 83.6%
(95%CI: 61-93)

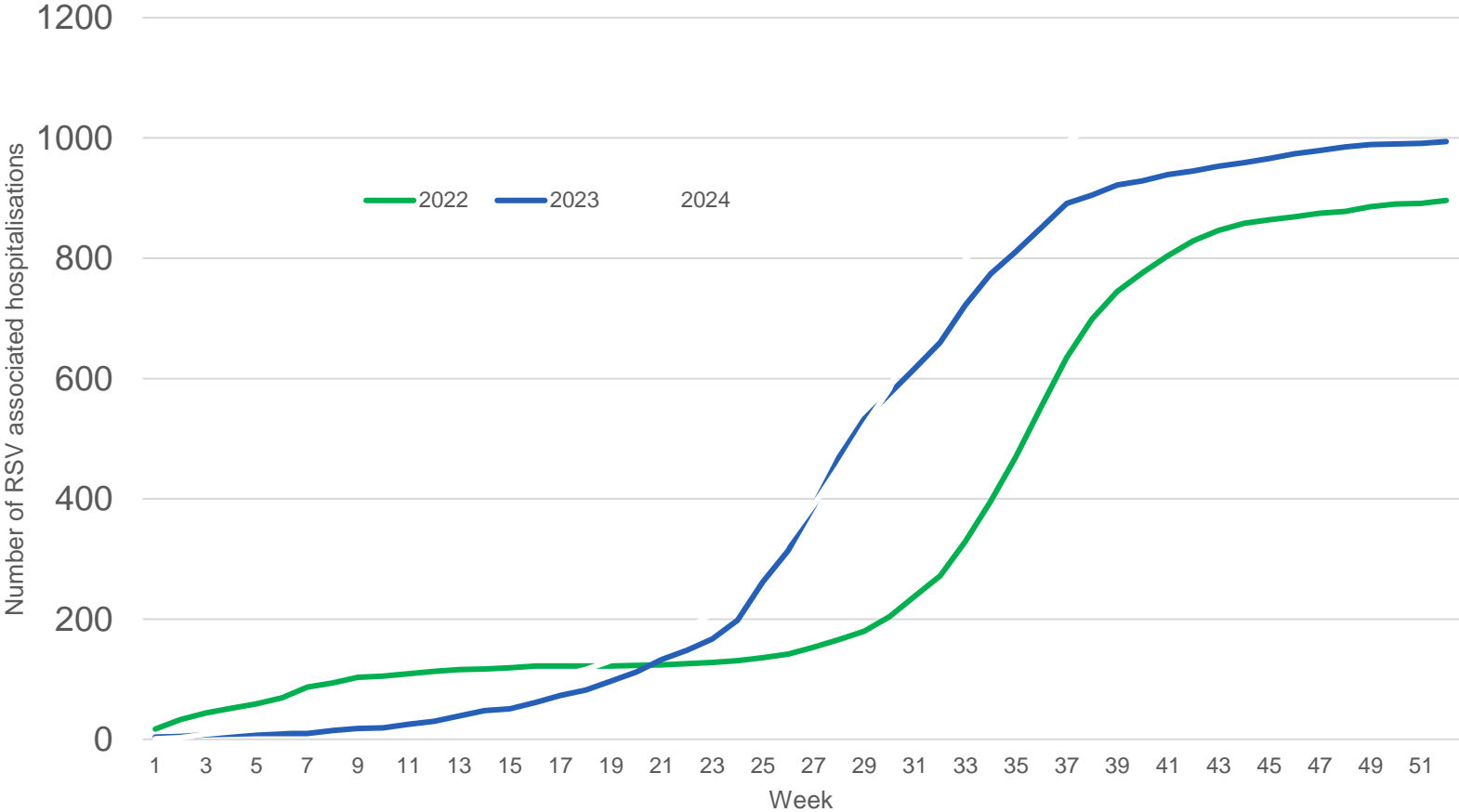


Dr Ushma Wadia

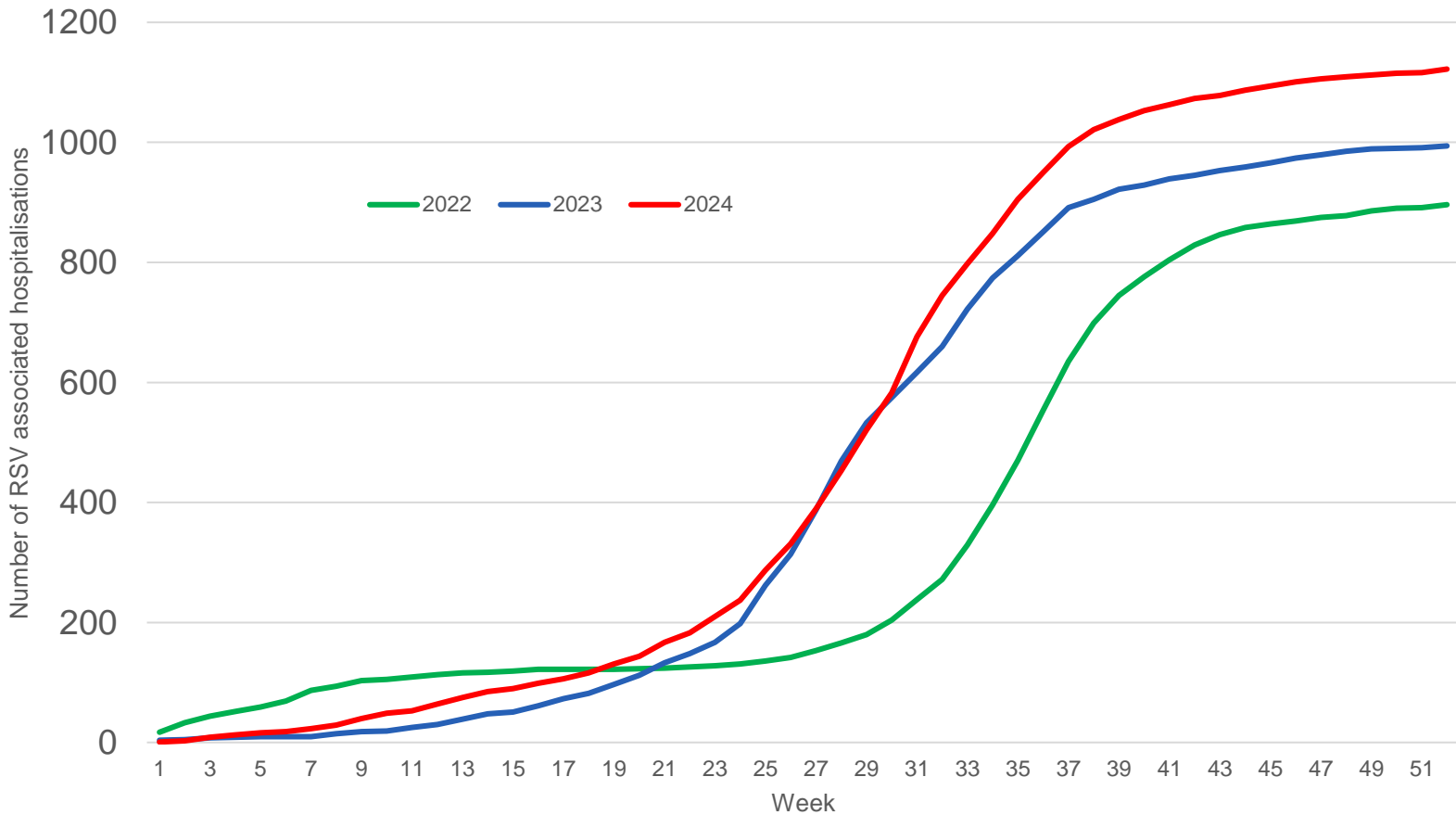


*adjusted by age group, sex, Aboriginality, comorbidity, preterm birth; grouped by month

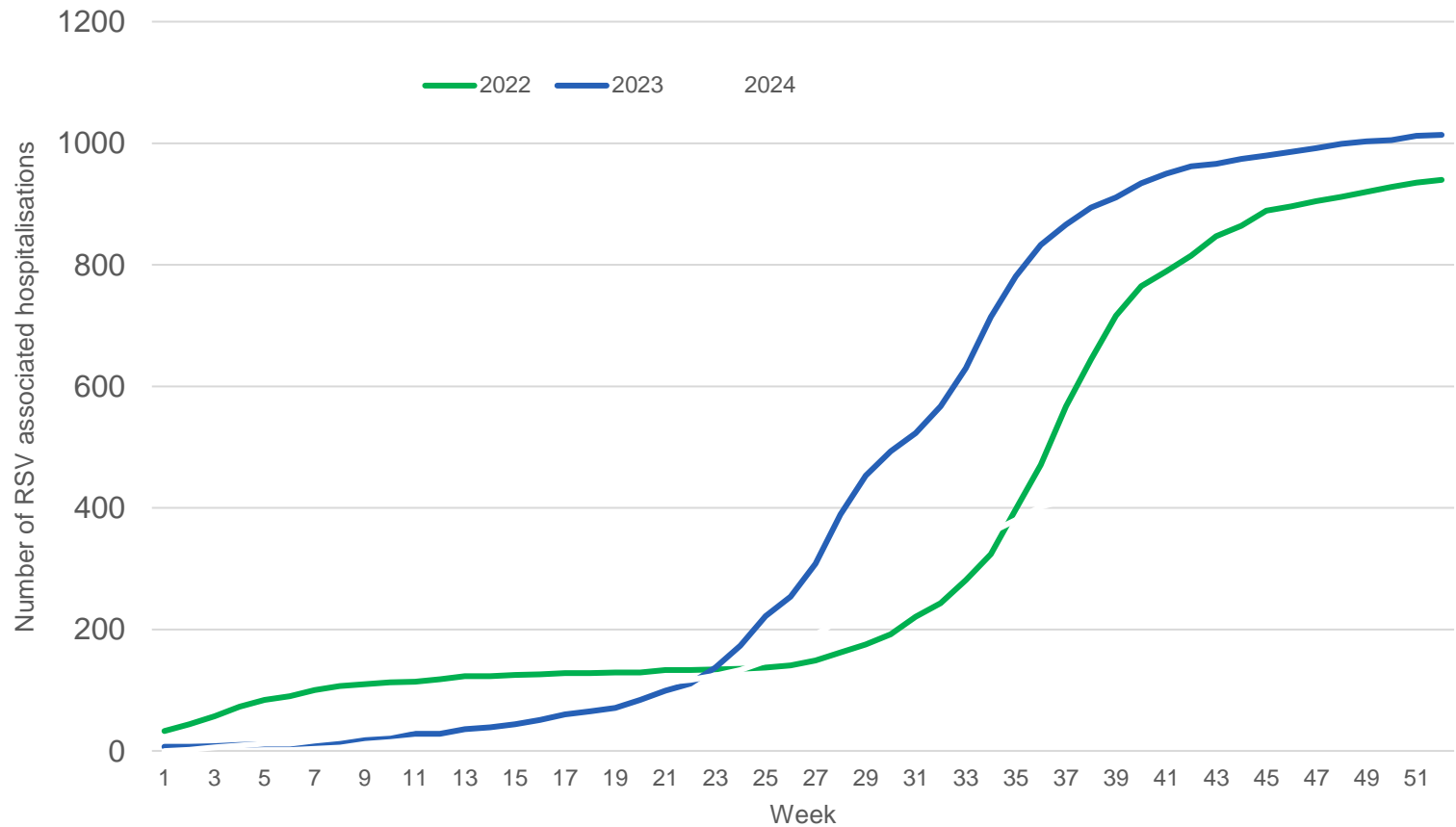
Cumulative number of RSV-associated hospitalisations in WA for children aged 1 to <5 years



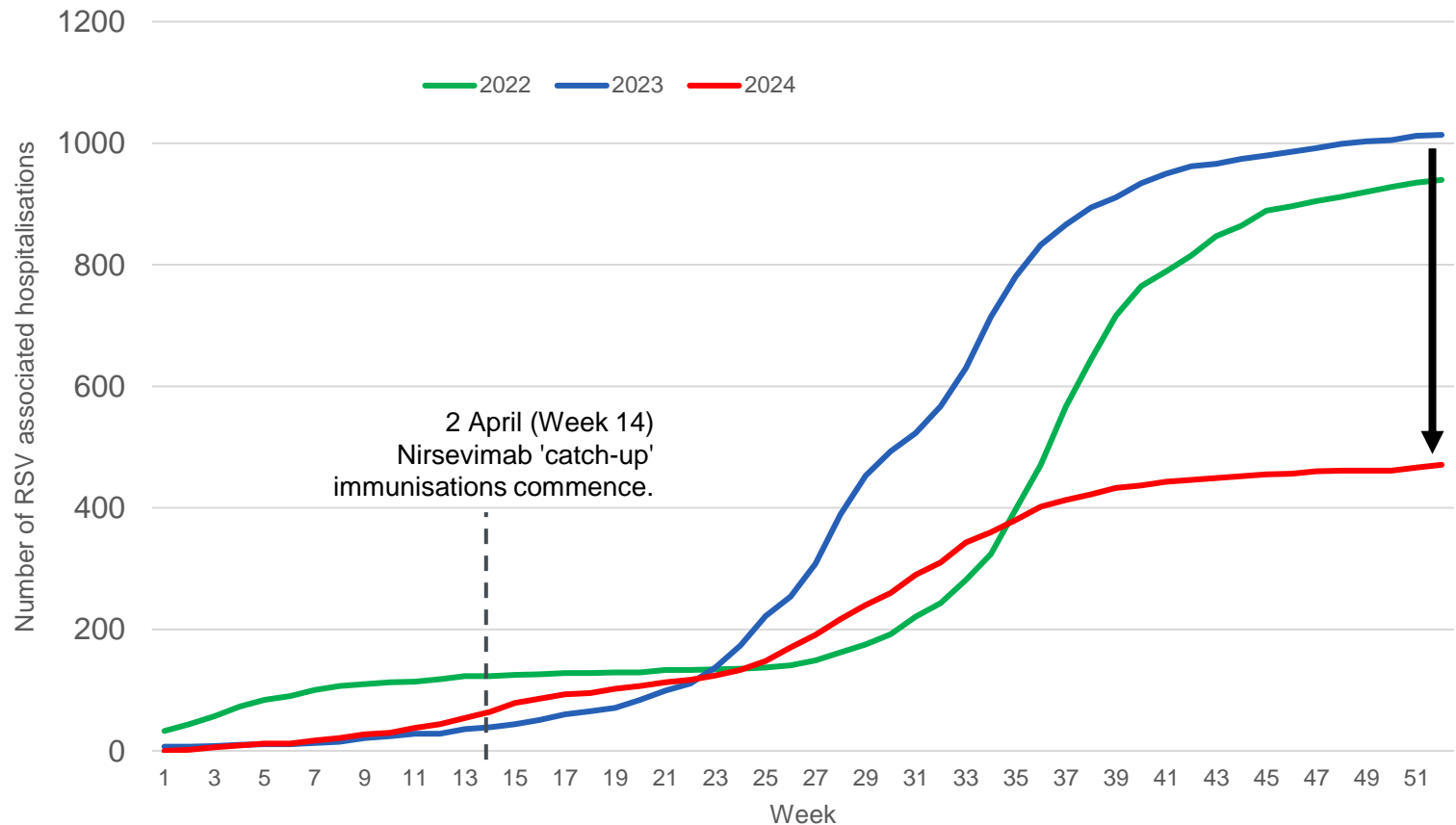
Cumulative number of RSV-associated hospitalisations in WA for children aged 1 to <5 years



Cumulative number of RSV-associated hospitalisations in WA for infants aged <1 year



Cumulative number of RSV-associated hospitalisations in WA for infants aged <1 year



Number of RSV-associated hospitalisations in WA, 1 May through 31 December, 2022-2024, by year of age.

| RSV-associated hospitalisations | 2022 | 2023 |
|---------------------------------|------|------|
| Age of child | | |
| 0 to < 1 year | 812 | 954 |
| 1 to < 2 years | 436 | 532 |
| 2 to < 3 years | 182 | 209 |
| 3 to < 4 years | 102 | 100 |
| 4 to <5 years | 54 | 79 |

At \$13,695 per infant hospitalisation that's \$ 6.9 million in savings

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Ratio of RSV hospitalisation **Infants < 1**: **Children aged 1-4**

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| | 1.04 | 1.05 |

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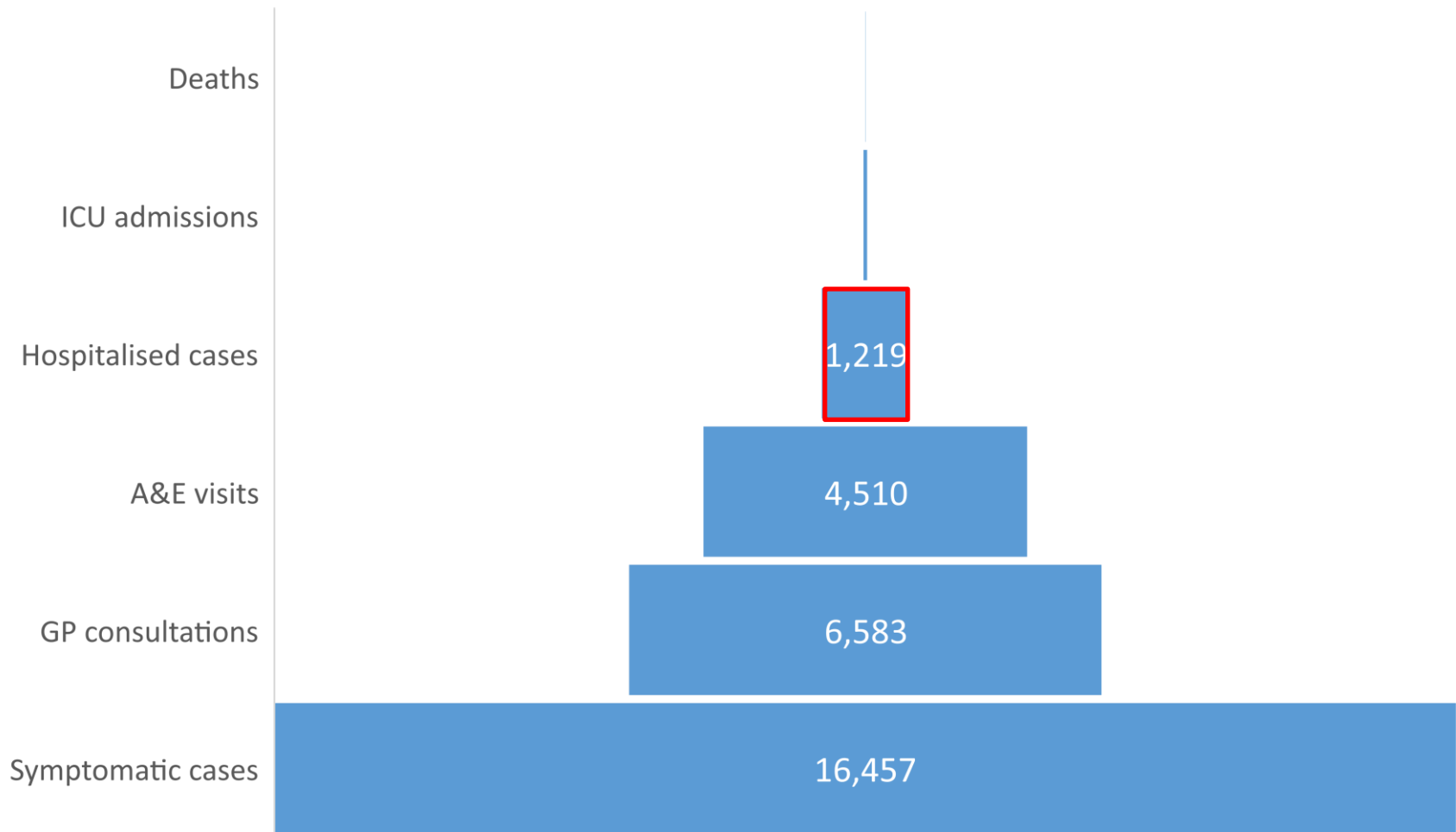
| RSV-associated hospitalisations | 2022 | 2023 | 2024 |
|---------------------------------|------|------|-------|
| Age of child | | | |
| 0 to < 1 year | 812 | 954 | |
| 1 to < 2 years | 436 | 532 | 540 |
| 2 to < 3 years | 182 | 209 | 276 |
| 3 to < 4 years | 102 | 100 | 117 |
| 4 to <5 years | 54 | 79 | 78 |
| | 1.04 | 1.05 | 1.045 |

Number of RSV-associated hospitalisations in WA, 1 May through 31 December, 2022-2024, by year of age.

| RSV-associated hospitalisations | 2022 | 2023 | 2024 |
|---------------------------------|------|------|-------|
| Age of child | | | |
| 0 to < 1 year | 812 | 954 | 1055 |
| 1 to < 2 years | 436 | 532 | 540 |
| 2 to < 3 years | 182 | 209 | 276 |
| 3 to < 4 years | 102 | 100 | 117 |
| 4 to <5 years | 54 | 79 | 78 |
| | 1.04 | 1.05 | 1.045 |

At \$13,695 per infant hospitalisation that's \$ 9.2 million in savings

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



Shenay Jones with her four-month-old daughter Lilah. Picture: Jackson Flindell



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-brainer" for her after seeing other children become very unwell from the condition.

Her third child, four-month-old 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 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 post-codes" 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

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

RSV prevention in 2025

There are now **two options** for preventing RSV illness in infants and young children.

Both of them involve providing the infant with preformed antibodies that can inactivate the RSV virus when the child is exposed to it.

Options for RSV prevention

Option A

Abrysvo - Maternal RSV Vaccination – This approach involves vaccinating the mother against RSV during her pregnancy.

The expectant mother then makes RSV-specific antibodies that are passed transplacentally to the foetus in utero.

Provides protection against infection for up to six months after the baby is born.

Options for RSV prevention

Option B

Beyfortus - RSV monoclonal antibody immunisation

This approach involves giving the infant or young child an injection containing specially formulated, ready-made, RSV-specific antibodies produced in a pharmaceutical laboratory.

The antibodies provide protection for at least 5 months.

WA 2025 RSV Infant and Maternal Immunisation Program

This year the WA RSV immunisation Program is **expanding** to include both options for preventing RSV illness in infants, i.e. infant immunisation with **Beyfortus** plus maternal vaccination with **Abrysvo**.



Option A

Abrysvo

Who is eligible for Abrysvo?

Abrysvo® will be provided for free through the NIP to eligible women from 28 to 36 weeks of pregnancy throughout the year.

How well does Abrysvo work in preventing RSV disease in infants?

For infants born to mothers who received Abrysvo®, a clinical trial found vaccine efficacy of 57% against hospitalisation for RSV disease for up to 6 months.

Vaccine efficacy was 70% against severe medically attended RSV-confirmed lower respiratory tract infection in their first 6 months of life.

How long does the protection by Abrysvo® last?

There is a gradual decline in protection derived from maternal RSV vaccination after birth due to waning antibody levels.

Protection against hospitalisation is significantly lower beyond the first 6 months of life.

No protection was observed between 6 and 12 months against severe medically attended RSV-confirmed lower respiratory tract infection.

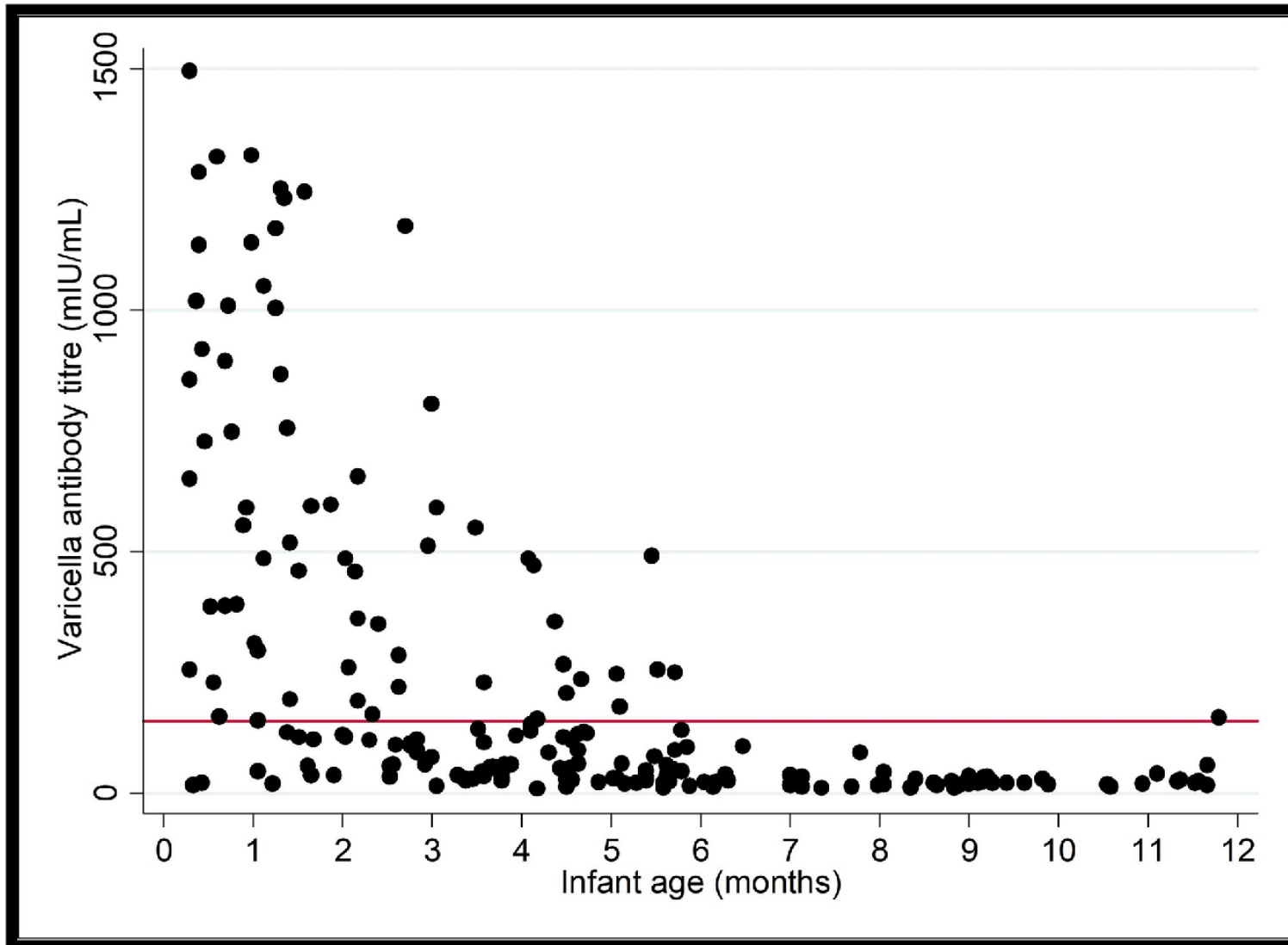


Fig 2. Scatterplot of the relationship between infant age in months and their varicella antibody concentration in mIU/mL. (N = 196) We

<https://www.semanticscholar.org/paper/Maternal-varicella-antibodies-in-children-aged-less-Bolotin-Hughes/51bd39d5ec4dd8777bc8321d57e647c9668cdfab>

How many doses of Abrysvo® do pregnant women need?

One. A single intramuscular 0.5mL injection of Abrysvo® is recommended for use in pregnant women to protect their infants.

When should pregnant women get Abrysvo®?

Administration is recommended at 28–36 weeks gestation.

If a pregnant woman is not vaccinated before 36 weeks gestation, they should receive the vaccine as soon as possible after 36 weeks gestation.

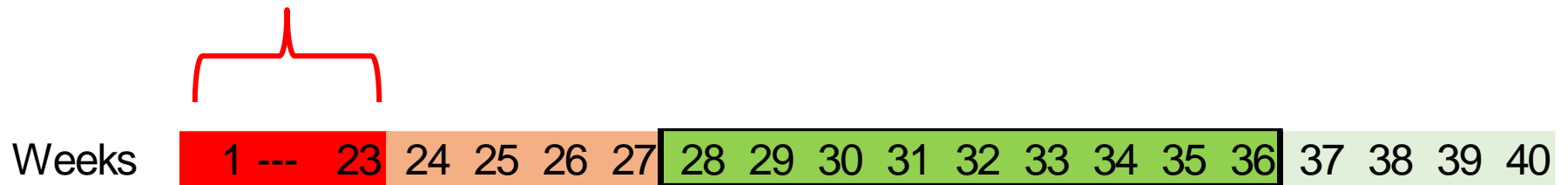
However, infants are not expected to be adequately protected unless they are born at least 2 weeks after their mother received the vaccine.

When should pregnant women get Abrysvo®?

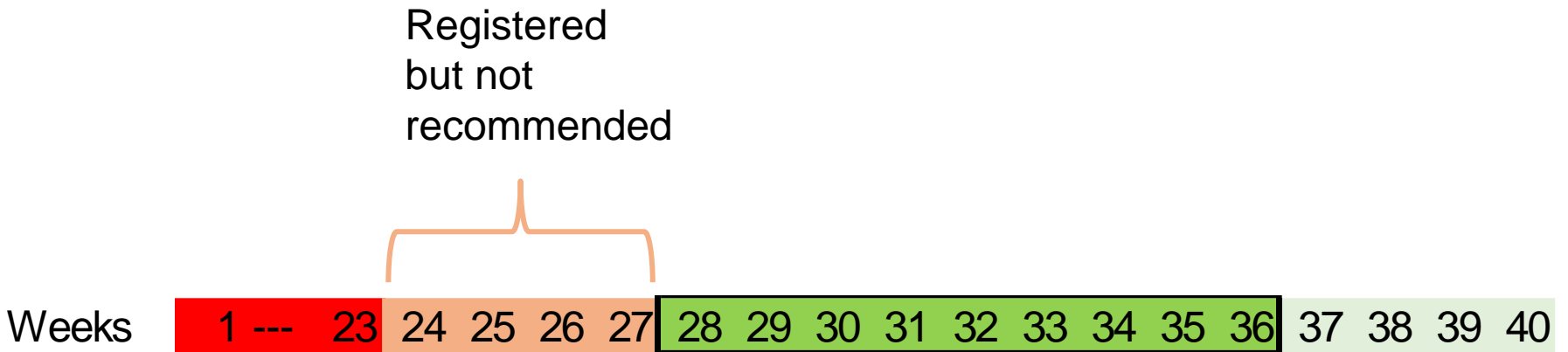


When should pregnant women get Abrysvo®?

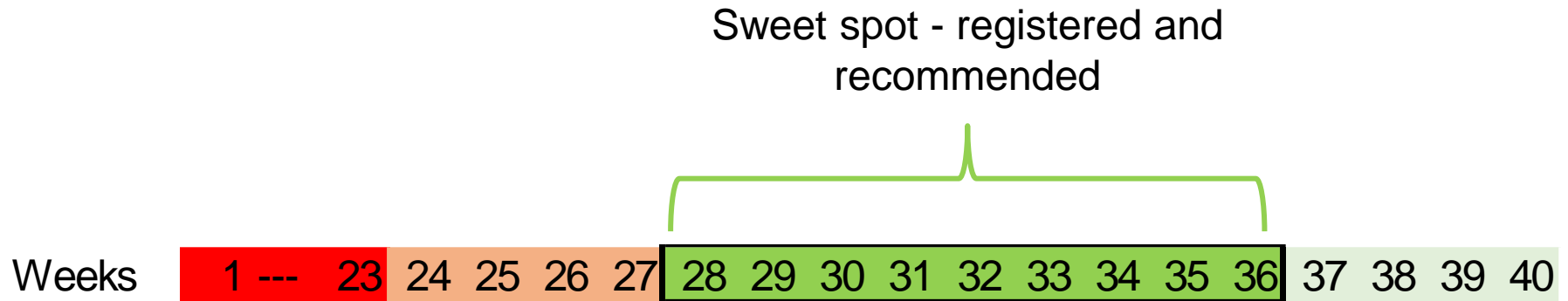
Don't go there



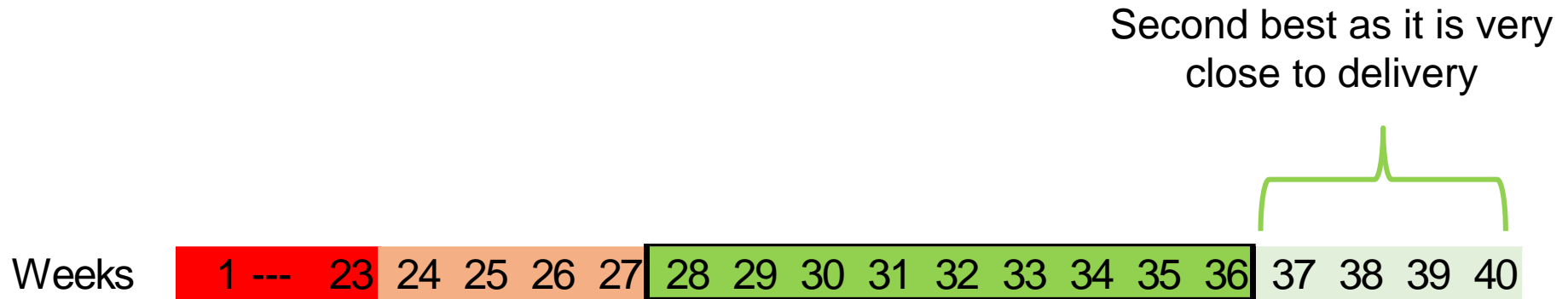
When should pregnant women get Abrysvo®?



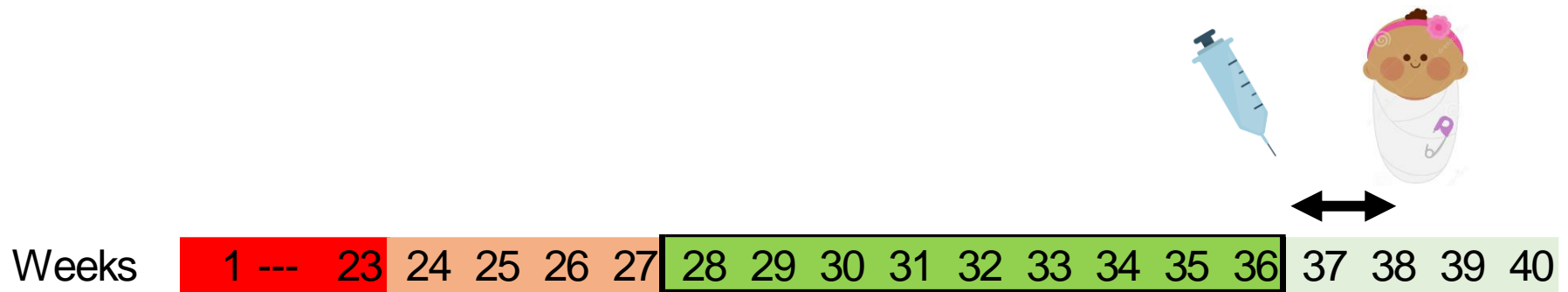
When should pregnant women get Abrysvo®?



When should pregnant women get Abrysvo®?



When should pregnant women get Abrysvo®?



Minimum of two weeks from
vaccination to delivery

Does Abrysvo® need to be administered twice if it was inadvertently given <28 weeks?

No.

If a pregnant woman receives Abrysvo® earlier than 28 weeks gestation, a repeat dose during the same pregnancy is not recommended.

Can Abrysvo® be co-administered with other maternal vaccinations?

Yes. Pregnant women can receive Abrysvo® at the same time as pertussis, influenza or COVID-19 vaccines.

No safety concerns were identified in studies of co-administration among non-pregnant women.

Where can pregnant women access Abrysvo vaccinations?

Pregnant women can be vaccinated at participating birthing hospitals, general practices, Aboriginal medical services, community health immunisation clinics and **local community pharmacies**.

Should women who are breastfeeding get an Abrysvo vaccination?

No. Women who are breastfeeding but not pregnant are not recommended to receive an RSV vaccine.

There are no theoretical safety concerns, but there is also no evidence that vaccination would protect the infant through breastfeeding alone.

What are the contraindications and precautions for Abrysvo®

The only absolute CONTRAINDICATIONS to Abrysvo® use are:

- anaphylaxis after a previous dose of Abrysvo®
- anaphylaxis after any component of Abrysvo®

Precautions -

Pregnant women are not recommended to receive Abrysvo earlier than 28 weeks gestation.

This is a precaution while waiting for further data on adverse events of special interest, particularly the risk of preterm birth.

The advice regarding gestational age at vaccination may be updated as further data become available.

If a woman has inadvertently been given Abrysvo between 24 and <28 weeks, they can be informed that safety data have indicated no statistically significant increase in adverse events compared with women who received the vaccine later in pregnancy.

What adverse events were observed giving Abrysvo to pregnant women?

In pregnant women aged 18-49 years who received Abrysvo between 24 and 36 weeks gestation:23,24

- 32–43% had injection site reactions, compared with 10–14% who received placebo.
- 62–63% had systemic adverse events, compared with 60–62% who received placebo. The most common symptom was fatigue.

Importantly, there was no difference in the rates of serious adverse events in pregnant women who received Abrysvo or their infants compared with placebo.

Can Arexvy - the other RSV vaccine registered by the TGA - be used to vaccinate pregnant women?

That's a hard No. Abrysvo® and Avrexy are different vaccines.

Arexvy is not registered for use in pregnant women and should not be given to pregnant women. There are limited data on inadvertent administration of Arexvy in pregnancy demonstrating potential safety concerns.

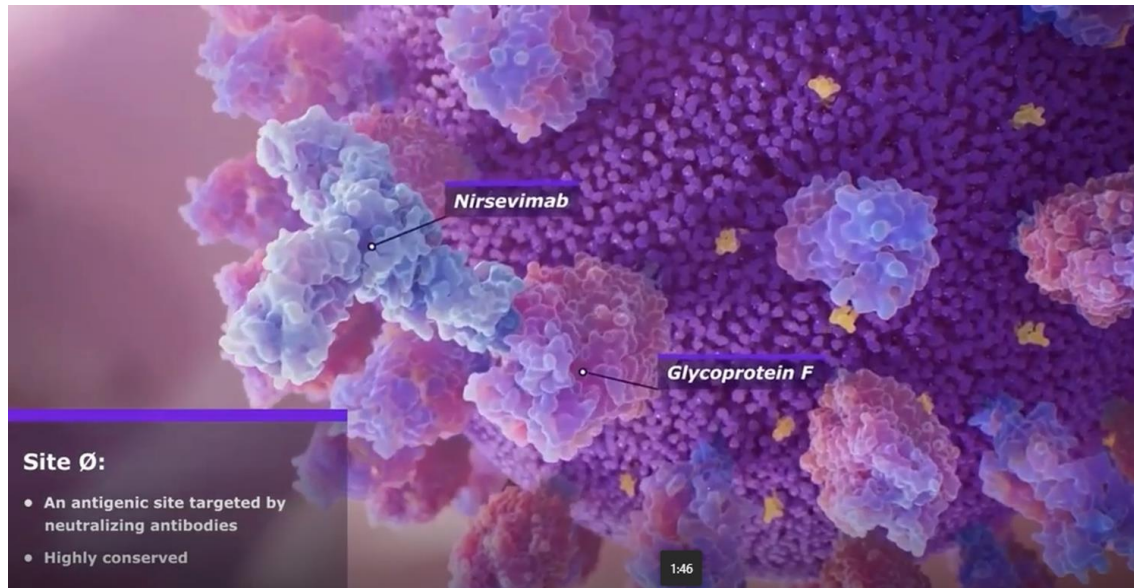
If a pregnant woman has inadvertently been given Arexvy, do not give Abrysvo.

Can infants be given the Abrysvo or Arexvy RSV vaccine?

No. Neither vaccine should be given to infants or children as there are no RSV vaccines currently licensed in this age group.

Option B

Beyfortus



Option B - RSV immunisation using Beyfortus.

Beyfortus is registered by the Therapeutic Goods Administration for the prevention of 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.

Who is eligible for Beyfortus in WA?

Beyfortus is recommended for infants who were:

- born to women who did not receive RSV vaccine during pregnancy
- born within 2 weeks of the mother receiving RSV vaccine during pregnancy
- infants with risk conditions for severe RSV disease, regardless of maternal vaccination
- infants born to vaccinated mothers with severe immunosuppression, where the immune response to maternally administered RSV vaccine was impaired

Who is eligible for Beyfortus in WA?

Beyfortus is recommended for infants who were:

- infants whose mothers received RSV vaccine in pregnancy but subsequently underwent a treatment that has led to loss of maternal antibodies (such as cardiopulmonary bypass or extracorporeal membrane oxygenation)
- children up to 24 months with risk conditions for severe RSV disease through their 2nd RSV season.
- Aboriginal children up to 24 months through their 2nd RSV season

What conditions are associated with increased risk of severe RSV disease in infants and young children?

1. **Preterm birth** <32 weeks gestational age
2. Haemodynamically significant **congenital heart disease**
3. **Significant immunosuppression**, such as from malignancy, solid organ transplant, haematopoietic stem cell transplant, or primary immune deficiencies such as severe combined immunodeficiency
4. **Chronic lung disease** requiring ongoing oxygen or respiratory support
5. **Neurological conditions** that impair respiratory function
6. **Cystic fibrosis** with severe lung disease or weight for length <10th percentile
7. **Trisomy 21** or another genetic condition that increases the risk of severe RSV disease

How well does Beyfortus work in preventing RSV disease in infants?

In clinical trials, Beyfortus was shown to be:

- 79% effective at preventing medically attended RSV-associated lower respiratory tract infection (LRTI).
- 80% effective at preventing RSV-associated LRTI with hospitalisation.
- 90% effective at preventing RSV-associated LRTI with ICU admission.

How long does the protection provided by Beyfortus last?

Beyfortus offers protection for at least 5 months, with early immunogenicity evidence showing some protection may remain for 6-12 months.

When should Beyfortus ® be administered?

The protective benefits of Beyfortus can be maximised if it is administered shortly before the start of - or during - the RSV season, typically April to September in most of WA.

What is the minimum interval between doses of Beyfortus® for Aboriginal children and children who have certain risk conditions who entering their second RSV season?

A minimum interval of 6 months is recommended between a 1st and 2nd season dose of Beyfortus.

Can Beyfortus be co-administered with other childhood vaccines?

Yes. Beyfortus can be safely administered at the same time as other routine childhood vaccines, including Hepatitis B vaccine birth dose, or the vaccines given at 2,4,6 or 12 months.

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

What are the contraindications and precautions for Beyfortus?

The only absolute CONTRAINDICATIONS to Beyfortus ® use are:

- anaphylaxis after a previous dose of Beyfortus
- anaphylaxis after any component of Beyfortus

Precautions

Serious hypersensitivity reactions, including anaphylaxis, have been observed rarely with other IgG1 monoclonal antibodies like Beyfortus.

What are some advantages and disadvantages of each approach?

Option A – Abrysvo advantages

Some advantages of maternal vaccination using Abrysvo are:

- Protection against RSV infection is already present the moment the child is born, i.e. there is no window of non-protection at the time when they are most vulnerable to serious RSV illness

Option A – Abrysvo disadvantages

Potential disadvantages of maternal vaccination using Abrysvo are:

- The protection the infant receives is dependent on several factors including the mother's ability to make sufficient antibodies and the time from vaccination to the birth.
- Some infants at very high-risk of severe RSV disease will still require Beyfortus even if the mother received Abrysvo during pregnancy.
- Maternal RSV vaccination cannot be used to protect high-risk children entering their second RSV season

Option B – Beyfortus Advantages

Advantages of using Beyfortus are:

- In contrast to maternal vaccination, the level of protection afforded by Beyfortus is not dependent on the ability of mother to mount an effective vaccination response or the time from vaccination to the birth.
- Beyfortus can be used to protect high-risk children entering their second RSV season.
- When Beyfortus is administered to infants just before the start of RSV season, or to infants shortly after birth during RSV season, protection throughout the period of highest exposure risk is assured.

Option B – Beyfortus disadvantages

Potential disadvantages of Beyfortus are:

- Protection is non-existent at birth, so any delay in administering Beyfortus after delivery will leave the child unprotected during that period.
- It may take several days to develop optimal protection from RSV illness after administration of Beyfortus.

The major challenge...

- Knowing which pregnant women received Abrysvo at least 2 weeks before delivery of the newborn

What if an infant whose mom was appropriately vaccinated with Abrysvo is inadvertently given Beyfortus?

What if an infant whose mom was appropriately vaccinated with Abrysvo is inadvertently given Beyfortus?

- For newborns with one of the 7 RSV risk conditions Beyfortus is actually recommended regardless of the mother vaccination status.
- No negative medical consequences are anticipated.
- But it is an unnecessary jab – and waste of expensive health care resources.

In summary...

What does the 2025 WA Expanded RSV Infant and Maternal Immunisation Program look like?

From 3 February 2025, Abrysvo® is available and recommended for all pregnant women from 28–36 weeks gestation.

In summary...

What does the 2025 WA Expanded RSV Infant and Maternal Immunisation Program look like?

From 1 April 2025, Beyfortus will be offered to:

In summary...

What does the 2025 WA Expanded RSV Infant and Maternal Immunisation Program look like?

From 1 April 2025, Beyfortus will be offered to:

Concept framework is...

1. Babies who are not – or likely not to be - adequately protected through maternal vaccination
2. Children entering their second RSV season who remain at risk of serious RSV disease

In summary...

What does the 2025 WA Expanded RSV Infant and Maternal Immunisation Program look like?

Beyfortus Group 1:

- as a catch-up program for babies born from 1 October 2024 to 30 September 2025 whose mothers ***did not receive*** Abrysvo® during pregnancy.
- infants with risk conditions for severe RSV disease, regardless of maternal vaccination status
- infants born to RSV vaccinated mothers with severe immunosuppression or a treatment that lowered antibody levels/or there was insufficient time to make enough antibodies before the birth (i.e. < 2 weeks) .

In summary...

What does the 2025 WA Expanded RSV Infant and Maternal Immunisation Program look like?

Beyfortus Group 2:

- to all Aboriginal children born on or after 1 October 2023 aged < 24 months
- to infants with specific high medical risk conditions entering their second RSV season born on or after 1 October 2023 aged < 24 months



Thank you!