

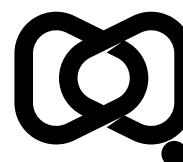


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Nirsevimab provides age-specific protection against RSV hospitalisation in the first year of life: a population-level study in Queensland, Australia

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Abstract

Nirsevimab, a long-acting monoclonal antibody with activity against respiratory syncytial virus (RSV), was introduced into the Queensland paediatric RSV prevention program in 2024. Using Queensland Notifiable Conditions Register (NoCS) data, we found that the infant cohort eligible for the nirsevimab program had lower RSV hospitalisation rates than comparable pre-program cohorts. The population-level impact of nirsevimab was greatest during the first month of life (incidence rate ratio [IRR]: 0.22; 95% confidence interval [95% CI]: 0.16–0.31; representing a 78% reduction in hospitalisation rate), with its magnitude gradually declining thereafter until nine months of age (IRR: 0.77; 95% CI: 0.62–0.96; a 23% reduction), following which the impact of nirsevimab on hospitalisation rate, with increasing age of the infant or child, was no longer statistically significant. An interrupted time-series analysis demonstrated an immediate 63% reduction in RSV hospitalisations following nirsevimab's introduction (IRR: 0.37; 95% CI: 0.23–0.60), showing a substantial population-level impact of the program in Queensland, Australia.

Keywords: respiratory syncytial virus; RSV; nirsevimab; vaccine effectiveness; interrupted time-series; population-level impact; hospitalisation; age-specific protection; Queensland

Introduction

Respiratory syncytial virus (RSV) is a leading global cause of hospitalisations in infants.¹ Australian RSV hospitalisation rates are highest amongst infants aged 0–< 6 months.² In Queensland, a publicly funded RSV prevention program, using the monoclonal antibody nirsevimab (Beyfortus, Sanofi/AstraZeneca), was implemented for infants from 15 April 2024, providing free and year-round immunisation to all infants as soon as practicable after birth.³ Infants not immunised in hospital could access a dose through primary care up until eight months of age. A catch-up program extended eligibility to all infants born on or after 1 February 2024 who were less than eight months of age. Infants aged 8–19 months who were born at less than 32 weeks' gestation, or who had specified complex medical conditions, remained eligible until 31 October 2024. Estimated nirsevimab coverage, during May to November 2024 inclusive, was 70–80%.^{4,5} From 1 December 2024, pregnant women in Queensland became eligible year-round for free RSV vaccination (Abrysvo, Pfizer) after 28 weeks' gestation.⁶ From this date, nirsevimab was recommended for infants born to women who had not received the RSV vaccine, or who had received

it less than two weeks before birth; and for those with conditions associated with a high risk of severe RSV disease, where nirsevimab can be administered at 8–< 24 months of age prior to their second RSV season.⁷

A community-level Queensland study reported a 64% reduction in RSV-positive polymerase chain reaction assay tests among infants aged 0–< 3 months following nirsevimab introduction,⁴ but did not quantify reductions in hospitalisations. Here we evaluate the population-level impact of the nirsevimab-only phase of Queensland's RSV prevention program on RSV hospitalisation, using age-specific, month-by-month analyses among infants aged 0–< 12 months.

Methods

Queensland is a state in the north-east of Australia, spanning the Tropic of Capricorn and covering 1,727,000 square kilometres. In Queensland, the RSV season differs geographically, typically peaking between December and May in the tropical north and between March and August in the subtropical south, with circulation continuing year-round.^{8–10} RSV became a notifiable condition in Queensland on 1 July 2021.¹¹

Laboratory confirmed RSV hospitalisations were obtained from the Queensland Notifiable Conditions Register (NoCS) from 1 January 2022 to 31 October 2025, including birthdate, public hospital admission status and notification date. Hospitalisation rates were calculated using Queensland monthly registered live births.¹²

Infants born between 1 April 2019 and 30 November 2024 were included in the following cohorts, based on nirsevimab birth-dose eligibility and age:

1. the post-nirsevimab cohort comprised infants aged 0 –< 12 months, born from 1 May to 30 November 2024, who were eligible for nirsevimab and representing infants born during the post-implementation period. As this cohort was born entirely after program commencement, all were eligible to receive nirsevimab as a birth dose rather than through the catch-up pathway;
2. the pre-nirsevimab cohort comprised infants aged 0 –< 12 months, born from 1 February 2021 to 31 March 2024; this group provided a historical comparison group prior to nirsevimab program implementation; and
3. nirsevimab-ineligible children aged 24 –< 36 months, born from 1 April 2019 to 30 November 2023, who were outside the age range eligible for the nirsevimab program. This cohort was used to assess whether changes in RSV hospitalisation following program implementation were specific to the age group targeted by nirsevimab. Eligibility dates were chosen to exclude children born after the maternal RSV vaccination became publicly funded on 1 December 2024.

The primary outcome was age-specific RSV hospitalisation, reported as incidence rates per 1,000 births by month of age (0 –< 12 months). Although the nirsevimab program commenced on 15 April 2024, we used 1 May 2024 as the start of the post-nirsevimab period, and 31 March 2024

as the end of the pre-nirsevimab period, because the primary outcome was calculated by month of age and expressed as incidence rates per 1,000 births. Using complete calendar-month birth cohorts allowed consistent monthly denominators to be calculated and avoided inclusion of a partial birth month. Infants born in April 2024 were excluded from both cohorts because they could not be reliably classified as pre- or post-birth-dose eligible, given the program's mid-month commencement on 15 April 2024. Accordingly, this birth month comprised a mixture of potentially exposed and unexposed infants. Including these individuals in either cohort could have resulted in exposure misclassification, thereby introducing bias into the estimated hospitalisation rates and the assessed impact of the nirsevimab program.

Poisson generalised linear models with log-link were fitted with the natural logarithm of livebirths as an offset. Cohort (pre-nirsevimab/post-nirsevimab) and age in months were included with an interaction term, and a quadratic age term accounted for non linearity. Harmonic terms were utilised to control for seasonality, and calendar year was included as a fixed effect. A Pearson chi-squared scale parameter was used to account for overdispersion. Results are presented as incidence rate ratios (IRRs) with 95% confidence intervals (95% CI). A separate model was fitted in nirsevimab-ineligible children aged 24 –< 36 months, to examine whether observed reductions were specific to eligible ages. As a secondary analysis, an interrupted time-series (ITS) design using Poisson generalised linear models assessed the population-level impact of nirsevimab on RSV hospitalisations in infants aged 0 –< 12 months. As a sensitivity analysis, we additionally excluded the first six months of 2022 (1 January to 30 June 2022 inclusive), representing the early post-notification period, to assess the potential influence of changes in notification ascertainment on the estimated pre-nirsevimab trend and counterfactual. Averted hospitalisations were estimated as the difference between the model-predicted counterfactual rate (i.e., the projected rate if pre-intervention trends had continued in the absence of the nirsevimab program) and the model-fitted rate. This difference was multiplied by the relevant birth-cohort denominator to estimate the number of hospitalisations averted each month. Analyses were performed using Stata v14.2 (StataCorp, College Station, TX). The Griffith University Human Research Ethics Committee approved this study (2024/787).

Results

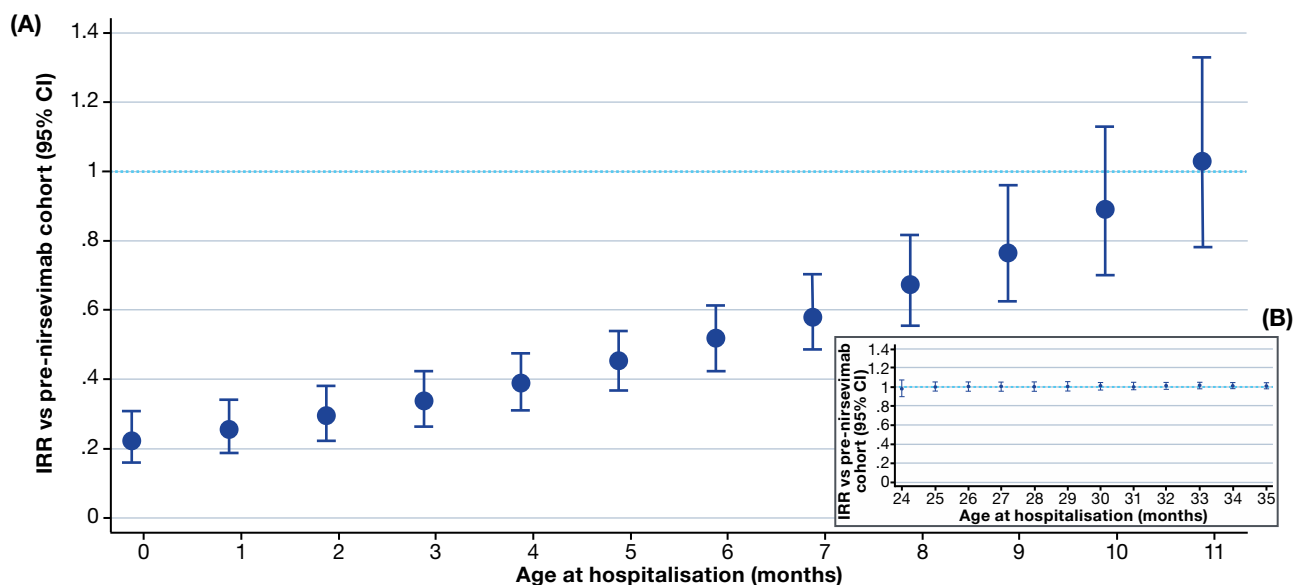
Overall, 4,446 laboratory-confirmed RSV hospitalisations were recorded amongst infants aged 0 –< 12 months between 1 January 2022 and 31 October 2025. Determination of pre- and post-nirsevimab cohort RSV hospitalisation rates, by age, allowed calculation of the age-dependent incidence rate ratio due to nirsevimab. The nirsevimab program offered the greatest population-level impact on RSV hospitalisations in the first month of life (IRR: 0.22; 95% CI: 0.16–0.31; corresponding to a 78% reduction in the RSV hospitalisation rate in this age group) and declined steadily to nine months of age (IRR: 0.77; 95% CI: 0.62–0.96; corresponding to a 23% reduction in this age group); at ages greater than nine months, the reductions in RSV hospitalisation rate were no longer statistically significant (Figure 1; Table 1). RSV hospitalisation rates among nirsevimab ineligible children aged 24 –< 36 months ($n = 1,360$) showed no corresponding change between the pre- and post-nirsevimab periods (IRR range: 1.01–1.02) (Figure 1).

Prior to nirsevimab's introduction, the RSV hospitalisation rates amongst infants aged 0 –< 12 months showed an increasing monthly

trend by ITS analysis (IRR: 1.04; 95% CI: 1.02–1.05), likely reflecting RSV rebound following curtailment of the public health control measures which had been introduced in the wake of the coronavirus disease 2019 (COVID-19) pandemic. Following nirsevimab's introduction, an immediate 63% reduction in RSV hospitalisation rates was observed (IRR: 0.37; 95% CI: 0.23–0.60). The post-introduction slope change (IRR: 0.99; 95% CI: 0.94–1.04; Table 2 and Figure 2), suggests a near-flat trajectory following the initial step-change reduction.

An estimated 1,240 RSV hospitalisations were averted during the 18-month period from 1 May 2024 to 31 October 2025 in Queensland infants aged 0 –< 12 months, born between 1 May and 30 November 2024 (Figure 3). In a sensitivity analysis excluding 1 January to 30 June 2022, the pre-nirsevimab trend was attenuated (IRR = 1.02, 95% CI: 0.99–1.03; $p = 0.06$), while the immediate reduction remained statistically significant, although attenuated (IRR = 0.51, 95% CI: 0.36–0.71; $p < 0.001$), with an estimated 882 hospitalisations averted (Table 2 and Figure 2).

Figure 1: Age-specific incidence rate ratios (IRR) for the post-nirsevimab vs pre-nirsevimab implementation cohorts, for respiratory syncytial virus (RSV) hospitalisation in (A) infants aged 0 –< 12 months, and (B) nirsevimab ineligible children aged 24 –< 36 months,^{a,b,c,d,e} Queensland, Australia



- a RSV hospitalisations were identified from the Queensland Notifiable Conditions Register (NOCS) dated 1 January 2022 – 31 October 2025.
- b For the ages 0 –< 12 months, the post-nirsevimab implementation cohort comprises infants with a birth date of 1 May – 30 November 2024; the pre-nirsevimab cohort comprises infants with a birth date of 1 February 2021 – 31 March 2024.
- c For the ages 24 –< 36 months, the post- and pre-nirsevimab implementation cohorts are nirsevimab-ineligible children with a birth date of 1 April 2019 – 30 November 2023.
- d IRRs are adjusted for age, seasonality (harmonic terms), and calendar year (secular trend).
- e 95% CI: 95% confidence interval.

Table 1: Age-specific respiratory syncytial virus (RSV) hospitalisation incidence rate ratio, for the post-nirsevimab vs pre-nirsevimab implementation cohorts, in infants aged 0 –< 12 months,^{a,b} Queensland, Australia

Age (months)	Post- vs. pre-nirsevimab cohort hospitalisation	
	Adjusted IRR ^{c,d}	95% CI ^{d,e}
< 1	0.22	0.16–0.31
1	0.25	0.19–0.34
2	0.29	0.23–0.38
3	0.33	0.27–0.43
4	0.39	0.31–0.48
5	0.44	0.36–0.54
6	0.51	0.42–0.61
7	0.58	0.49–0.70
8	0.67	0.55–0.82
9	0.77	0.62–0.96
10	0.89	0.70–1.12
11	1.01	0.77–1.33

a RSV hospitalisations were identified from the Queensland Notifiable Conditions Register (NOCS) dated 1 January 2022 – 31 October 2025.

b Post-nirsevimab cohort: infants with birth dates during 1 May – 30 November 2024; pre-nirsevimab cohort: infants with birth dates during 1 February 2021 – 31 March 2024.

c IRR: incidence rate ratio, adjusted for age, seasonality (harmonic terms), and calendar year (secular trend).

d **Bold** items indicate significant results.

e 95% CI: 95% confidence interval.

Table 2: Interrupted time-series (ITS) results for the respiratory syncytial virus (RSV) hospitalisation incidence rate ratio, for the post-nirsevimab vs pre-nirsevimab implementation cohorts, in infants aged 0 –< 12 months,^{a,b} Queensland, Australia

Parameter	Primary ITS ^{c,d,e} (1 January 2022 – 31 October 2025)		Sensitivity ITS ^{c,d,e} (1 July 2022 – 31 October 2025)	
	Adjusted IRR	95% CI	Adjusted IRR	95% CI
Pre-nirsevimab trend	1.04	1.02–1.05	1.02	0.99–1.03
Immediate level change	0.37	0.23–0.60	0.51	0.36– 0.71
Gradual effect, per month	0.99	0.94–1.04	1.00	0.97–1.03

a RSV hospitalisations were identified from the Queensland Notifiable Conditions Register (NOCS) dated 1 January 2022 – 31 October 2025.

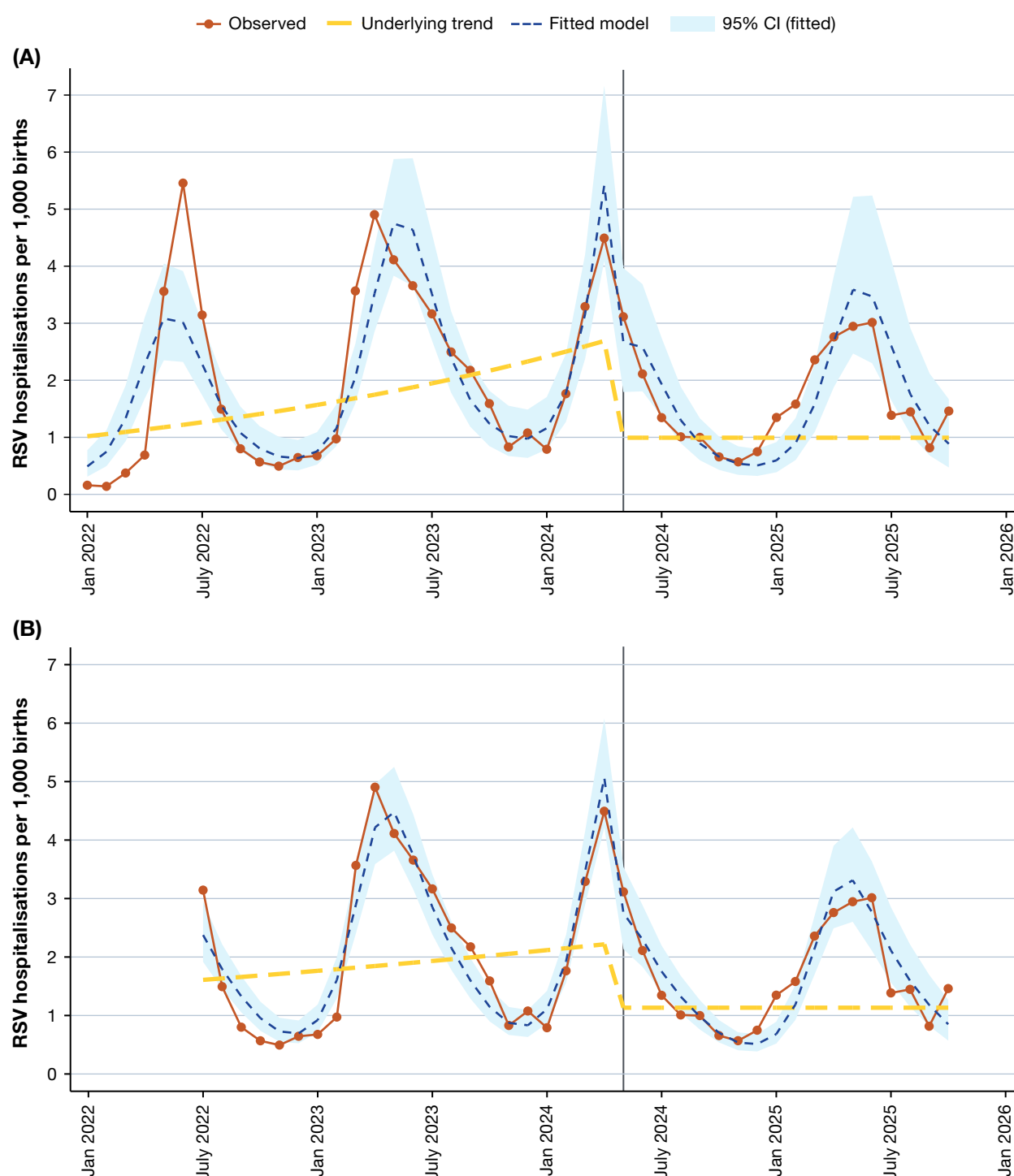
b Post-nirsevimab implementation cohort comprises infants with a birth date of 1 May – 30 November 2024; pre-nirsevimab implementation cohort comprises infants with a birth date of 1 February 2021 – 31 March 2024.

c IRR: incidence rate ratio, adjusted for seasonality and secular trend.

d **Bold** items indicate significant results.

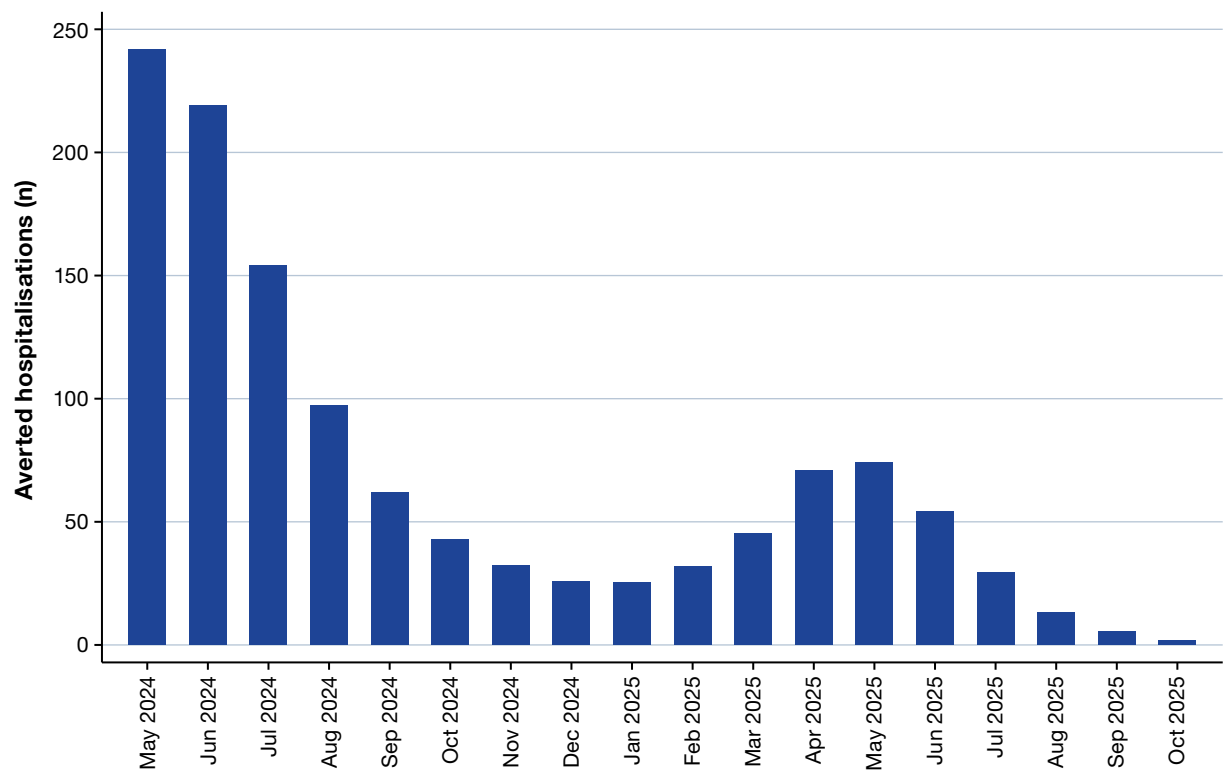
e 95% CI: 95% confidence interval.

Figure 2: Primary (A) and sensitivity (B) interrupted time-series (ITS) analyses for respiratory syncytial virus (RSV) hospitalisation incidence rate ratios, for the post-nirsevimab vs pre-nirsevimab implementation cohorts, in infants aged 0 –< 12 months,^{a,b,c,d,e} Queensland, Australia



- RSV hospitalisations were identified from the Queensland Notifiable Conditions Register (NOCS) dated 1 January 2022 – 31 October 2025.
- The primary ITS analysis (A) included monthly RSV hospitalisation rates per 1,000 live births during the period 1 January 2022 to 31 October 2025. The sensitivity ITS analysis (B) excluded the observations for 1 January – 30 June 2022, to assess the potential influence of the early post-notification period on the estimated pre-nirsevimab trend and counterfactual.
- Post-nirsevimab cohort comprises infants with a birth date of 1 May – 30 November 2024; pre-nirsevimab cohort comprises infants with a birth date of 1 February 2021 – 31 March 2024.
- The vertical line on each chart indicates the start of the post-nirsevimab analysis period (1 May 2024); the program itself commenced on 15 April 2024, with April 2024 births excluded.
- 95% CI: 95% confidence interval.

Figure 3: Calculated monthly averted respiratory syncytial virus (RSV) hospitalisations associated with nirsevimab among infants aged 0–<12 months,^{a,b,c} 1 May 2024 – 31 October 2025, Queensland, Australia



- a RSV hospitalisations were identified from the Queensland Notifiable Conditions Register (NOCS) dated 1 January 2022 – 31 October 2025.
- b Post-nirsevimab cohort comprises infants with a birth date of 1 May – 30 November 2024.
- c Averted hospitalisations were calculated as described within the text.

Discussion

This study demonstrated a significant real-world population-level impact of nirsevimab on RSV hospitalisation in Queensland infants. The greatest population-level reduction in RSV hospitalisations was observed during the first months of life, with the magnitude of the reduction progressively diminishing with increasing age. This gradual age-specific decline in population-level impact is biologically plausible given the pharmacokinetic profile of nirsevimab;¹³ although, as individual dosing dates were not available to us, this pattern reflects population-level impact rather than individual-level waning. The clinical and public health value of this study lies in quantifying the magnitude of this population-level impact month-by-month during the first year of life. This may have implications for program planning, including the timing of nirsevimab administration and strategies to protect infants at highest risk of RSV hospitalisation under routine program conditions in Australia.

Clinical trials using nirsevimab demonstrate high efficacy (77–83%) against RSV hospitalisation following a single dose, with protection sustained across a single RSV season, consistent with its prolonged half life and pharmacokinetic profile.¹³ However, trials are not able to demonstrate how protection varies by age in real-world settings, and effectiveness has generally been reported at the seasonal level rather than across finer age intervals. Early Australian studies using individual-level test negative or cohort designs have similarly reported high overall effectiveness during the first RSV season.^{14,15} In contrast, our study reports population-level impact using an ecological design, in a setting with an estimated nirsevimab coverage of 70–80%.^{4,5} Our findings are broadly consistent with a recent report from New South Wales (NSW),¹⁶ which demonstrated a 43% reduction in RSV hospitalisations in infants less than six months of age following implementation of a statewide RSV prevention program. The NSW analysis assessed population-level program impact reflecting combined maternal RSV vaccination and nirsevimab, while our Queensland cohort was born before maternal RSV vaccination became available under the National Immunisation Program and received nirsevimab only, providing an estimate of its standalone population-level impact. The observed reduction in our study (63% among infants aged 0 –< 12 months) extends the age range over which the population-level impact of nirsevimab has been described, including beyond the first six months of life reported in the NSW

study. Our findings also provide additional insights by quantifying the population-level impact of nirsevimab across months of age in the first-year of life, offering a more detailed characterisation of the pattern of protection observed under program conditions. The absence of corresponding changes in RSV hospitalisation rates among nirsevimab ineligible children aged 24 –< 36 months supports the interpretation that the age specific patterns observed among infants reflect nirsevimab associated protection rather than changes in healthcare-seeking behaviour or secular trends in RSV epidemiology.

This study has several strengths. Statewide surveillance data provide complete capture of laboratory-confirmed RSV hospitalisations, including during the peak RSV season, in Queensland. A major strength of our study is using two complementary analytical methods. The primary age-specific analysis assessed whether the population-level reduction in RSV hospitalisations varied by age, while the secondary ITS estimated changes in population-level RSV hospitalisation rates following the introduction of nirsevimab.

However, several limitations should be noted. First, the population-level impact of nirsevimab may have been underestimated in our analyses. RSV detection is influenced by clinician testing practices, and the pre-nirsevimab cohort included infants born after 1 February 2024 as well as high-risk infants, with both groups eligible for catch-up vaccination. Second, in the absence of information about dose timing, we were unable to specifically assess any impact on the population-level duration of protection caused by those doses given in the community after discharge from hospital. Third, individual level immunisation data were not available; therefore, our findings reflect the impact of the program's introduction rather than the individual effectiveness of the monoclonal antibody. Fourth, the steep pre-program trend likely reflects temporary post-COVID dynamic effects upon RSV,¹⁷ as well as potential changes in case ascertainment following the inclusion of RSV as a notifiable condition in Queensland in July 2021. Although the counterfactual was conservatively specified and a sensitivity analysis excluding the early post-notification period yielded consistent findings, absolute averted hospitalisations should be interpreted with caution. Finally, the analysis was restricted to government-funded hospital admission data.

Admissions occurring in private hospitals were not captured because these data are not routinely available to NoCS, which may result in incomplete ascertainment of hospital admissions. However, according to national data from the Australian Institute of Health and Welfare, public hospitals account for approximately 92% of all emergency-driven acute admissions.¹⁸ Given the acute nature of RSV hospitalisations in infants, excluding private hospital admissions is unlikely to substantially affect our estimates.

Here we have demonstrated the population-level impact of the nirsevimab program. Our findings have implications for the ongoing evaluation of RSV prevention strategies, particularly in settings with prolonged or unpredictable RSV seasons, where the timing of RSV activity may not align consistently with a fixed seasonal administration schedule. In such settings, consideration of the timing of nirsevimab delivery relative to periods of greatest RSV risk may be particularly important to ensure protection during periods when infants are at highest risk of hospitalisation.

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Declaration of interests

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Author contributions

Conceptualisation: AE, KG, SBL, RSW; collected and provided the data: MR, ACS; methodology: AE and RSW; software: AE; formal analysis: AE, writing-initial draft: AE; writing-review and editing: KG, MR, SBL and RSW. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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