

Who is at risk of a respiratory syncytial virus hospitalisation? A linked, population-based birth cohort analysis in children aged less than 5 years



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Summary

Background Respiratory syncytial virus (RSV) is a major cause of acute lower respiratory infections globally in children under five years. With the development of RSV prevention strategies, understanding risk factors and relation to age and population is useful for deciding the type of program implemented.

Methods We used a probabilistically-linked population cohort of children born in Western Australia from 2010 to 2020 and hospitalised before age five years from 2010 to 2021. The primary outcome was the first laboratory-confirmed RSV-hospitalisation. Risk factor exposures included perinatal, socio-demographic, household, environmental, congenital, and comorbid conditions antecedent to RSV-hospitalisation. Adjusted hazard ratios (aHR) and population attributable fractions (PAF) were calculated using survival analysis techniques and Cox regression.

Findings Risk factors for RSV-hospitalisation in 365,582 children included demographic (male sex, Aboriginal ethnicity), perinatal (younger maternal age, maternal asthma, prematurity, maternal prenatal smoking) household/environmental (household size, season of birth), and comorbid and congenital conditions (cardiovascular defects, Trisomy 21 and cerebral palsy). Aboriginal and preterm children had an excess risk of hospitalisation at every age group. Larger households and being born moderate-late preterm had the highest PAFs (36.90% [95% CI: 35.01%, 38.74%] and 7.40% [95% CI: 6.75%, 8.04%]). While the risk of hospitalisation for children with some comorbid and congenital conditions was high (immunological conditions, aHR: 3.94 [95% CI: 2.98, 5.23], respiratory system defects, aHR: 3.13 [95% CI: 1.87, 5.25]), the PAFs were relatively small (1.70% [95% CI: 1.53%, 1.86%] and 0.40% [95% CI: 0.30%, 0.49%]).

Interpretation While children with comorbid conditions were at higher risk of RSV-hospitalisation, the importance of socio-demographic risk factors, particularly modifiable factors such as maternal prenatal smoking and household transmission, should not be undervalued. Our analysis provides information for funders, vaccine policy makers, parents/carers, and immunisation providers.

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Research in context

Evidence before this study

With the development and implementation of two respiratory syncytial virus (RSV) preventive products (maternal vaccine and monoclonal antibody), deciding whether to implement universal vs. risk-based programs with either immunisation product and determining eligibility criteria for the latter is contingent on understanding risk factors by age and population and identifying children at highest risk of hospitalisation. Previous analyses on risk factors have included a more limited number of comorbid and congenital conditions. We sought to build on other work in this area. We searched PubMed from database inception to 1 October 2024, for literature, with no language restrictions, using the search terms: a) ((RSV [Title/Abstract]) OR (Respiratory syncytial virus [Title/Abstract])) AND ((child [Title/Abstract]) OR (children [Title/Abstract])) AND (risk factor [Title/Abstract]). This search returned 23 results, none of which included an estimation of population attributable fractions (PAF). A further search was conducted with the above search terms and including PAFs: ((RSV [Title/Abstract]) OR (Respiratory syncytial virus [Title/Abstract])) AND ((child [Title/Abstract]) OR (children [Title/Abstract])) AND (risk factor [Title/Abstract]) AND ("population attributable fraction" [Title/Abstract]). There were no studies

identified when the search term "population attributable fraction" was added.

Added value of this study

In addition to quantifying the effect size of a wide range of perinatal, socio-demographic, household/environmental factors, and comorbid and congenital conditions through adjusted Cox proportional hazard models in children <5 years, we also estimated their contribution at a population level by calculating PAFs. Our analysis is an expanded evaluation of risk factors by age group and in Aboriginal children. Analysis by age subgroup provides guidance on risk profiles by age and informs current and future interventions.

Implications of all the available evidence

While the risk of hospitalisation for children with some comorbid and congenital conditions is higher than children without these conditions, they had relatively small PAFs, meaning that the proportion of hospitalised cases attributed to that risk factor at a population level is relatively small. In contrast, some socio-demographic factors such as maternal prenatal smoking, younger pregnancies, and household size made greater contributions at a population level. Both measures are important in guiding decision making for immunisation policy.

Introduction

The last two years has seen rapid progress in the development and implementation of a safe and effective maternal bivalent preF fusion protein vaccine¹ (Abrysvo®) and a long-acting monoclonal antibody (mAb, nirsevimab/Beyfortus®)² against respiratory syncytial virus (RSV), the most common cause of acute lower respiratory infections and childhood pneumonia in children <5 years.³ Both preventive products provide excellent passive protection for preterm and term infants.^{1,2,4} Both products have now been licensed in several countries, but current international recommendations are highly heterogeneous with different timing for the delivery of vaccine and mAbs, and different implementation strategies.^{5,6} In Australia, in 2025, the administration of nirsevimab is state-funded and offered in every state/territory, while the maternal RSVpreF vaccine was included in the National Immunisation Program,⁷ in a hybrid approach. In addition to RSVpreF and nirsevimab, other mAb's are also in development,⁸ as are future RSV immunisation candidates for toddlers, and may be available in the future.⁹

Deciding whether to implement universal vs. risk-based programs with either immunisation product

and determining eligibility criteria for the latter is contingent on understanding risk factors by age and population and identifying children at highest risk of hospitalisation. A maternal vaccine only program (e.g. UK⁶) will have a different impact to a combination of maternal vaccine and mAb. Knowing who should be recommended for a mAb, for example, in the second RSV season, is important for funders, vaccine policy makers, parents and carers, and immunisation providers. Quantifying the risk of hospitalisation by maternal and perinatal factors, gestational and calendar age at immunisation, climate, and child comorbidity, is critical to determining a clinically and cost-effective immunisation strategy, protecting those most vulnerable. Furthermore, some risk factors for hospitalisation are relevant to maternal immunisation (e.g. maternal age, season of birth), while others will be more pertinent to decisions around mAbs (e.g. prematurity, birth defects). Assessment of immunisation programs across ages, risk groups, and seasons is also a necessary component of a baseline cost assessment to inform the cost-effectiveness of future RSV therapeutics, an essential evaluation of any public health intervention.

Previous analyses on risk factors synthesised in a recent systematic review included a limited number of comorbid and congenital conditions.¹⁰ Australian data on risk factors for hospitalisation are relatively sparse^{11,12} and little research has focused on Aboriginal children,^{13,14} children with developmental anomalies,¹⁵ and comorbidities.^{12,16} We therefore sought to conduct an expanded risk factor analysis to identify children at risk of an RSV-hospitalisation. We also took the opportunity to assess the Western Australian (WA) Department of Health's (DOH) eligibility criteria for medically at-risk children for the 2024 nirsevimab program.

Methods

Setting and study design

WA covers the western third of Australia with a population of 2.7 million residents; 77.8% of residents live in the capital city, Perth, and surrounds. Aboriginal and/or Torres Strait Islander people (hereafter referred to respectfully as Aboriginal) comprise 6.4% of the population.¹⁷ Owing to the geographical size of WA, there are two main climate zones. In temperate WA (southern regions), the Southern winter respiratory season typically spans from May to September, peaking in mid-winter (July). The north of the state (Kimberley and Pilbara regions, [SFigure 1](#)) experiences a tropical/sub-tropical climate with year-round RSV activity and has a higher proportion of Aboriginal residents.

Data sources

We used statewide, linked, whole-of-population data from the Respiratory Infections Linked Data Platform¹⁸ of all births in WA between 1 January 2010 and 31 December 2020. Data sources include the Midwives Notifications System (MNS), comprising state-wide perinatal information on >99% of births in WA, birth and death registries, the hospital morbidity data collection, and respiratory pathogen testing from the state's sole public pathology provider, PathWest. Data were probabilistically linked using best practice protocols through Data Services at the WA DOH.¹⁹

Hospital admission records for all children aged <5 years with an admission and discharge date between 1 January 2010 and 31 December 2021 were included to match availability of laboratory data. Inter-hospital transfers were collapsed and considered the same admission.¹⁸ Positive and negative respiratory specimen testing records with specimen collection dates between 1 January 2010 and 31 December 2021 ([SFigure 2](#)) were temporally linked: specimen collection within 4 days of hospital admission.¹⁸ Previous work by our team examining testing practices in both metropolitan and regional locations for hospitalisations due to RSV and influenza has shown that younger children have higher rates of testing, positivity and incidence. Other

predictors of testing were preterm birth and residence in a remote location.²⁰ Children with birth defects were identified from the WA Register of Developmental Anomalies (WARDA)²¹ and children with cerebral palsy were identified from the Cerebral Palsy Register (WARDA-CP). Aboriginal status was derived using a validated algorithm.²²

Outcome measures

Our primary outcome of interest was the first laboratory-confirmed RSV hospitalisation in the relevant age group: infants (birth to <12 months of age), children in their second year of life (12–<24 months), and older children (2–<5 years of age).

Exposures

We included socio-demographic, maternal, and child risk factors based on published literature and data availability.¹⁸ Risk factor exposures included perinatal (maternal age, maternal asthma status, maternal pre-natal smoking, delivery mode, gestational age at birth, and plurality), socio-demographic (sex, Aboriginal status, socioeconomic status at birth, accessibility index¹⁸), and household/environmental factors (household size, season of birth). Accessibility index is an index developed by the University of Adelaide and used by the Australian Bureau of Statistics as the official classification of remoteness. It is a measure of relative geographic access to services and excludes any consideration of socioeconomic status, rurality, and population size factors. Season of birth was defined as: spring (1 September–30 November); summer (1 December–28 February); autumn/fall (1 March–31 May); winter (1 June–30 August). We also examined residence in tropical locales in Northern WA (Kimberley and Pilbara regions) as a risk factor. We did not examine out-of-home care, childcare attendance, multi-generational households, and palivizumab use as risk factors. Chronic medical conditions were identified using International Classification of Diseases, 10th edition, Australian Modification (ICD-10-AM) principal and additional diagnostic codes in hospital data antecedent to the RSV-hospitalisation and classified into broad categories: immunological, inflammatory, cardiac, chronic respiratory, neurological, renal, and metabolic conditions, and children with developmental delay ([STable 1](#)). Major congenital defects were identified in WARDA using British Paediatric Association (BPA) codes and classified into system categories (nervous system, cardiovascular, respiratory system, gastrointestinal, urogenital and chromosomal defects), as well as individual defects (cystic fibrosis, trisomy 21, and cerebral palsy, [STable 2](#)). The need for supplemental oxygen, a marker of respiratory insufficiency/failure, was identified from Australian Classification of Health Interventions, 12th edition, procedure codes ([STable 3](#), [SText 1](#)).

Exclusions

We excluded all stillbirths, births with gestational age missing or <20 weeks, birthweight <400 g or missing, and any missing data on covariates of interest to conduct a complete case analysis.

Assessment of WA Department of Health eligibility criteria

We assessed the WA DOH eligibility criteria for medically at-risk children for the 2024 nirsevimab program (SText 2, STable 4). As before, children with the stated medical conditions were identified using ICD-10-AM codes in principal and additional diagnoses antecedent to RSV-hospitalisation. We were unable to identify children on chronic corticosteroid treatment or children on diuretic therapy as pharmacological data are not recorded in the hospital morbidity data collection for multi-stay admissions. In assessing these eligibility criteria settings, we did not consider age or seasonality in our assessment but focused instead on underlying medical/congenital conditions.

Statistical analysis

We used all laboratory-confirmed RSV hospitalisations as the numerator and person-time at-risk as the denominator to calculate age-specific incidence rates per 1000 person-years, stratified by Aboriginal status, with 'age' being age at admission at the time of an RSV-hospitalisation. However, to calculate unadjusted and adjusted hazard ratios (aHR) with 95% confidence intervals (CI), we retained only the first RSV-associated hospitalisation in each age group. Thus, the first RSV-associated hospitalisation in the first year of life was the first laboratory-confirmed RSV hospitalisation for the child. The first RSV-associated hospitalisation in the second year was the first RSV-hospitalisation between the age of 12–<24 months. Chronic medical conditions identified in admissions antecedent to the first RSV-hospitalisation were collapsed into a single flag for analysis.

Time-at-risk was calculated as the time from the a) date of birth (infant cohort, 0–<12 months), b) age 12 months (12–<24 month old cohort), or c) age 24 months (2–<5 year old cohort) to the earliest of a) date of admission of the first RSV-hospitalisation in that age group, b) death, c) when the child's age reached the end of that age group period (infants-12 months, children in their second year-24 months, older children-5 years), or d) end of the study period. Cox regression models and survival analysis techniques were used for all analyses. Cox regression models are appropriate when time-to-event data are available (in this case, admission to hospital from an RSV infection, or death), and when individuals can be followed up longitudinally, so censoring can be properly handled (in this case censored at completion of a particular age or end of study period). Hazard ratios represent the relative

incidence rate of an event between groups (in this case children with and without the condition). Variables with a p-value of ≤ 0.2 in univariate analysis were included in multivariate models. The final models were adjusted for all or some socio-demographic and perinatal risk factors: maternal age, maternal prenatal smoking, maternal asthma, mode of delivery, gestational age at birth, plurality, child's sex, Aboriginal status, socioeconomic status, accessibility index, number of previous pregnancies (as a proxy for household size), and season of birth. Population attributable fractions (PAF) and their 95% CI were calculated for risk factors with an elevated HR using the punafcc module in Stata, which uses Miettinen's formula to estimate PAFs based on adjusted models using survival data.²³ Separate models were constructed for Aboriginal and non-Aboriginal children, stratified by age group. For older children, we included a binary covariate for previous infant RSV hospitalisation. A similar approach was used to analyse the Department of Health's 2024 criteria for high-risk conditions (birth to time of diagnosis for infants, first birthday to age 5 years for older children, with conditions identified antecedent to diagnosis). All analyses were performed using STATA software, version 17.

Ethics approval

Ethical approval was obtained from the WA Department of Health Human Research Ethics Committee (HREC) (RGS2762, 12/06/2024) and the WA Aboriginal Health Ethics Committee (HREC 437, 02/09/2024). As the study utilised de-identified linked administrative data, a waiver of informed consent was granted by the WA Department of Health HREC.

Role of the funding source

The study sponsors had no role in the study design, in the collection, analysis, and interpretation of data; in the writing of the report; and in the decision to submit the paper for publication.

Results

The cohort comprised 371,381 children born in WA between 1 January 2010 and 31 December 2020. We excluded 2553 (0.69%) stillbirths, 46 (0.01%) children with infant weight <400 g or missing, 23 (0.01%) children with missing gestational age, and 2532 (0.68%) non-WA resident children at the time of their birth (Fig. 1). Outcome data consisted of 556,767 hospital admissions linked to laboratory testing data and included 37,925 (6.8%) admissions tested for RSV (8316, 20.9% RSV-positive). We excluded 14,543 records outside of the study period, 74,092 records of children admitted after the age of five years, and 19,171 non-resident hospitalisations. Multiple admissions were collapsed. Our final analytic cohort comprised

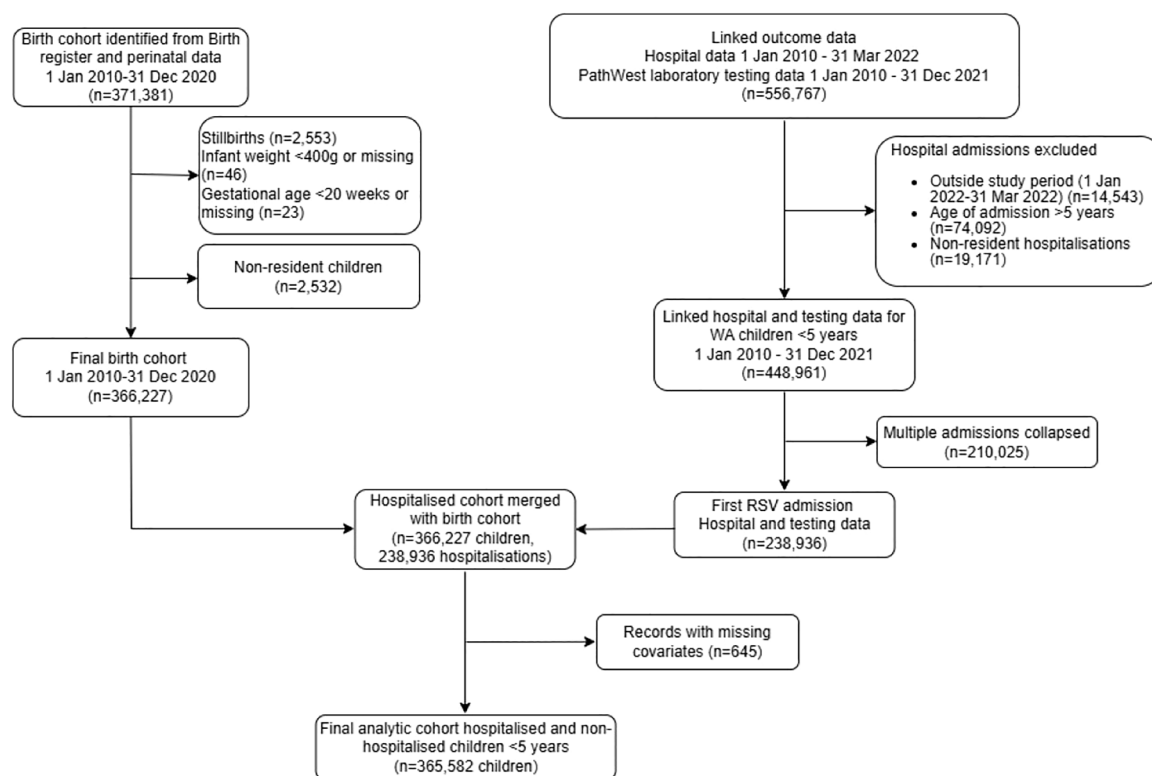


Fig. 1: Cohort selection.

365,582 children, of whom 238,484 were hospitalised at least once.

Overall, 24,118 (6.60%) of the cohort were Aboriginal and 31,557 (8.63%) were born preterm (Table 1). Mothers of Aboriginal children were more likely to be younger (3973, 16.5% aged <20 years vs. 7040, 2.1% of non-Aboriginal mothers) and smoke during pregnancy (10,127, 42.0% vs. 25,649, 7.5%). Infants had the highest RSV-associated hospitalisation rates compared to older children (infants: 14.47 per 1000 child-years [95% CI: 14.09, 14.86] vs. children 12–<24 months old: 5.06 per 1000 years [95% CI: 4.83, 5.31]), with Aboriginal infants hospitalised at three times the rate as non-Aboriginal infants (Table 2).

Infants (0–<12 months)

The highest aHRs were seen with preterm infants born ≤ 32 weeks, infants in larger households, infants of younger mothers, infants born in autumn/winter, Aboriginal infants, and infants residing in outer regional areas of WA (Fig. 2a, STable 5). When considering comorbid and congenital conditions, infants with Trisomy 21, cerebral palsy, or cardiovascular, nervous system, or chromosomal defects had a higher risk of an RSV-associated hospitalisation. In contrast, infants of larger households (PAF: 36.90%, [95% CI: 35.01, 38.74]) and infants born in autumn (PAF:

15.16%, [95% CI: 13.65, 16.64]) had the highest PAFs (Fig. 3a, STable 5).

Children 12–<24 months

Preterm children continued to be at higher risk of RSV-associated hospitalisation in the second year of life, particularly extremely preterm children (aHR: 4.67 [95% CI: 3.20, 6.80]) and very preterm children (aHR: 3.85 [95% CI: 2.91, 5.09], Fig. 3a, STable 5). Aboriginal children (aHR: 1.59 [95% CI: 1.34, 1.89]), children hospitalised with RSV in infancy (aHR: 2.30 [95% CI: 1.83, 2.89]), and children with immunological, chronic respiratory, and neurological conditions, or children with developmental delay had a higher risk of RSV-hospitalisation (STable 5). Children with cardiovascular, respiratory system, and chromosomal defects, including Trisomy 21, also had a higher risk of an RSV-associated hospitalisation. In contrast, being born in autumn or winter was not a significant risk factor in the second year of life. Children from larger households, preterm children, and Aboriginal children had the largest PAFs (Fig. 3b, STable 5).

Children 2–<5 years

Children born preterm ≤ 32 weeks gestation were more likely to be hospitalised between 2 and <5 years of age (extremely preterm aHR: 4.76 [95% CI: 3.17, 7.13]; very

Characteristic	Total N = 365,582 n (%)	Non-aboriginal N = 341,464 n (%)	Aboriginal N = 24,118 n (%)	Odds ratio (95% CI)
<i>Maternal age groups</i>				
<20 years	11,013 (3.0%)	7040 (2.1%)	3973 (16.5%)	2.92 (2.79, 3.06)
20–24 years	47,212 (12.9%)	39,563 (11.6%)	7649 (31.7%)	Reference
25–29 years	101,236 (27.7%)	94,864 (27.8%)	6372 (26.4%)	0.35 (0.34, 0.36)
30–34 years	125,734 (34.4%)	121,793 (35.7%)	3941 (16.3%)	0.17 (0.16, 0.17)
35 years or more	80,387 (22.0%)	78,204 (22.9%)	2183 (9.1%)	0.14 (0.14, 0.15)
<i>Maternal smoking during pregnancy</i>				
No	329,806 (90.2%)	315,815 (92.5%)	13,991 (58.0%)	Reference
Yes	35,776 (9.8%)	25,649 (7.5%)	10,127 (42.0%)	8.91 (8.66, 9.17)
<i>Maternal Asthma</i>				
No	333,551 (91.2%)	311,805 (91.3%)	21,746 (90.2%)	Reference
Yes	32,031 (8.8%)	29,659 (8.7%)	2372 (9.8%)	1.15 (1.10, 1.20)
<i>Socioeconomic status at birth¹⁸</i>				
0–20% (most disadvantaged)	73,644 (20.1%)	60,859 (17.8%)	12,785 (53.0%)	4.65 (4.47, 4.84)
21–40%	75,738 (20.7%)	70,570 (20.7%)	5168 (21.4%)	1.62 (1.55, 1.70)
41–60%	76,925 (21.0%)	73,602 (21.6%)	3323 (13.8%)	Reference
61–80%	77,080 (21.1%)	75,106 (22.0%)	1974 (8.2%)	0.58 (0.55, 0.62)
81–100%	62,195 (17.0%)	61,327 (18.0%)	868 (3.6%)	0.31 (0.29, 0.34)
<i>Remoteness index¹⁸</i>				
Major city	285,098 (78.0%)	275,065 (80.6%)	10,033 (41.6%)	Reference
Outer regional	28,906 (7.9%)	27,275 (8.0%)	1631 (6.8%)	1.64 (1.55, 1.73)
Inner regional	26,673 (7.3%)	22,853 (6.7%)	3820 (15.8%)	4.58 (1.41, 4.77)
Rural/remote	16,481 (4.5%)	12,269 (3.6%)	4212 (17.5%)	9.41 (9.04, 9.80)
Very remote	8424 (2.3%)	4002 (1.2%)	4422 (18.3%)	30.29 (28.90, 31.56)
<i>Delivery mode</i>				
Vaginal	178,493 (48.8%)	163,147 (47.8%)	15,346 (63.6%)	Reference
Instrumental	53,566 (14.7%)	51,543 (15.1%)	2023 (8.4%)	0.42 (0.40, 0.44)
Elective Caesarean	67,664 (18.5%)	65,153 (19.1%)	2511 (10.4%)	0.41 (0.39, 0.43)
Emergency Caesarean	65,859 (18.0%)	61,621 (18.0%)	4238 (17.6%)	0.73 (0.71, 0.76)
<i>Child's sex^a</i>				
Male	188,055 (51.4%)	175,518 (51.4%)	12,537 (52.0%)	1.02 (1.00, 1.05)
Female	177,515 (48.6%)	165,935 (48.6%)	11,580 (48.0%)	Reference
<i>Preterm birth</i>				
Term birth	334,025 (91.4%)	313,402 (91.8%)	20,623 (85.5%)	Reference
Moderate to late preterm birth	27,723 (7.6%)	24,788 (7.3%)	2935 (12.2%)	1.80 (1.73, 1.87)
Very preterm birth	2568 (0.7%)	2218 (0.6%)	350 (1.5%)	2.40 (2.14, 2.69)
Extremely preterm birth	1266 (0.3%)	1056 (0.3%)	210 (0.9%)	3.02 (2.60, 3.51)
<i>Season of birth</i>				
Summer	89,508 (24.5%)	83,530 (24.5%)	5978 (24.8%)	Reference
Autumn	93,974 (25.7%)	87,658 (25.7%)	6316 (26.2%)	1.01 (0.97, 1.04)
Winter	90,821 (24.8%)	84,789 (24.8%)	6032 (25.0%)	0.99 (0.96, 1.03)
Spring	91,279 (25.0%)	85,487 (25.0%)	5792 (24.0%)	0.95 (0.91, 0.98)
<i>Number of previous pregnancies</i>				
None	98,044 (26.8%)	92,509 (27.1%)	5535 (22.9%)	Reference
One	112,419 (30.8%)	106,932 (31.3%)	5487 (22.8%)	0.86 (0.83, 0.89)
Two or more	155,119 (42.4%)	142,023 (41.6%)	13,096 (54.3%)	1.54 (1.49, 1.59)
<i>Plurality</i>				
Singleton	355,420 (97.2%)	331,982 (97.2%)	23,438 (97.2%)	Reference
Multiple	10,162 (2.8%)	9482 (2.8%)	680 (2.8%)	1.06 (0.94, 1.10)
<i>Year of birth</i>				
2010	30,971 (8.47%)	28,980 (8.49%)	1991 (8.26%)	0.99 (0.93, 1.06)
2011	31,860 (8.71%)	29,849 (8.74%)	2011 (8.34%)	0.97 (0.91, 1.03)
2012	33,535 (9.17%)	31,440 (9.21%)	2095 (8.69%)	0.96 (0.90, 1.02)
2013	34,051 (9.31%)	31,936 (9.35%)	2115 (8.77%)	0.96 (0.90, 1.02)
2014	34,855 (9.53%)	32,596 (9.55%)	2259 (9.37%)	0.97 (0.91, 1.03)
2015	34,612 (9.47%)	32,432 (9.50%)	2180 (9.04%)	Reference

(Table 1 continues on next page)

Characteristic	Total N = 365,582 n (%)	Non-aboriginal N = 341,464 n (%)	Aboriginal N = 24,118 n (%)	Odds ratio (95% CI)
(Continued from previous page)				
2016	35,329 (9.66%)	33,087 (9.69%)	2242 (9.30%)	0.98 (0.92, 1.04)
2017	33,845 (9.26%)	31,579 (9.25%)	2266 (9.40%)	1.04 (0.97, 1.10)
2018	32,694 (8.94%)	30,457 (8.92%)	2237 (9.28%)	1.06 (1.00, 1.13)
2019	32,498 (8.89%)	30,187 (8.84%)	2311 (9.58%)	1.10 (1.04, 1.17)
2020	31,332 (8.57%)	28,921 (8.47%)	2411 (10.00%)	1.20 (1.13, 1.28)

Abbreviation: CI: confidence interval. ^a12 children had indeterminate gender status.

Table 1: Demographic characteristics of the cohort.

preterm aHR: 3.37 [95% CI: 2.35, 4.84]) compared to term children (STable 6). Children with immunological, chronic respiratory, and neurological conditions, central nervous system and cardiovascular defects were more likely to be hospitalised with RSV in their third, fourth or fifth year of life. Season of birth was not a significant risk factor for hospitalisation for older children, but children hospitalised with RSV in infancy were twice as likely to be hospitalised in later childhood (aHR: 1.97 [95% CI: 1.45, 2.68]). Male and Aboriginal children, children from larger households, children born of older mothers, preterm children, and children born in autumn and winter had the highest PAFs. Children aged 2–<5 years with immunological, chronic respiratory, and neurological conditions, children with developmental delay, and children with cardiovascular defects had the highest PAFs (STable 6).

Risk by aboriginal status

There were no appreciable differences in the risk of hospitalisation between Aboriginal and non-Aboriginal children (STables 7–9), although small numbers of infants with comorbid conditions or congenital defects made it difficult to compare all conditions between the two populations. Aboriginal infants exposed to prenatal smoking, infants of younger mothers, and infants residing in northern WA had the highest PAFs, reflecting the higher prevalence of prenatal smoking and younger pregnancy in Aboriginal mothers

(Table 1). Older Aboriginal children 12–<24 months of age continued to be impacted by maternal prenatal smoking and contributed a higher PAF than non-Aboriginal children.

Assessment of Department of Health 2024 eligibility criteria

Finally, we separately assessed the RSV-hospitalisation risk and PAFs in medically at-risk children according to the WA DOH eligibility criteria for the 2024 nirsevimab program (SText 2, STable 4). Infants with chronic respiratory conditions or Trisomy 21 had the highest aHRs; however, when assessing the prevalence of medical conditions in the population, chronic respiratory conditions had the highest PAFs (17.94% [95% CI: 17.57, 18.30; Table 3). On closer examination, only 6.4% of admissions flagged antecedent to an RSV hospitalisation in an infant year were infants with chronic lung disease of prematurity (SText 2, dot point 1, under chronic respiratory conditions). The majority of admissions flagged that were included under this classification were children who had received some form of respiratory support (dot point 2). In older children, being born premature, children with immunological conditions, and children with Trisomy 21 had the highest risk of hospitalisation and thus the highest aHRs (Table 3). However, as with infants, older children with chronic respiratory conditions requiring supplemental oxygen (as defined in the 2024

Age group	All children N = 8165		Non-Aboriginal children N = 6587		Aboriginal children N = 1281		Incidence rate ratio (95% CI)
	n	Rate per 1000 (95% CI)	n	Rate per 1000 (95% CI)	n	Rate per 1000 (95% CI)	
0–<6 months	3920	21.33 (20.67, 22.01)	3058	17.92 (17.30, 18.57)	646	53.39 (49.43, 57.67)	2.98 (2.73, 3.24)
6–<12 months	1386	7.58 (7.19, 7.99)	1046	6.13 (5.77, 6.51)	264	21.86 (19.37, 24.66)	3.56 (3.10, 4.08)
12–<24 months	1772	5.06 (4.83, 5.31)	1521	4.65 (4.43, 4.89)	248	10.81 (9.55, 12.25)	2.32 (2.02, 2.66)
24–48 months	1087	1.27 (1.20, 1.35)	962	1.20 (1.13, 1.28)	123	2.24 (1.88, 2.67)	1.86 (1.53, 2.25)
0–<12 months	5306	14.47 (14.09, 14.86)	4104	12.03 (11.66, 12.40)	910	37.64 (35.27, 40.17)	3.12 (2.91, 3.36)
12–<60 months	2859	2.37 (2.29, 2.46)	2483	2.20 (2.12, 2.29)	371	4.77 (4.30, 5.28)	2.16 (1.93, 2.41)

Abbreviation: CI: confidence interval. ^aAll laboratory-confirmed RSV-hospitalisations were included in the calculation of age-specific incidence rates, with age being age at admission at the time of RSV-hospitalisation.

Table 2: Age-specific rates for all RSV-hospitalisations^a in children under 5 years of age, 2010–2021.

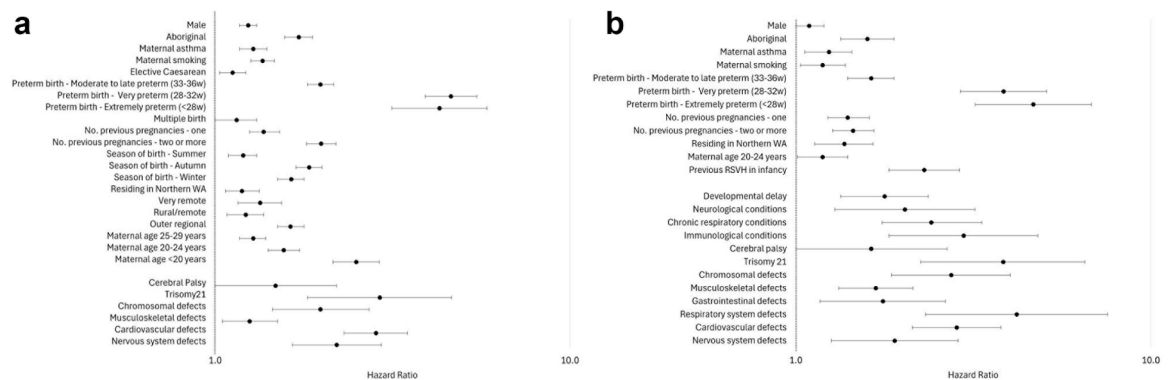


Fig. 2: Adjusted hazard ratios for perinatal and socio-demographic, comorbid, and congenital risk factors for hospitalisation due to RSV in a) infants aged less than 12 months, and b) older children aged 12–24 months in Western Australia, 2010–2021. Abbreviation: RSVH: Hospitalisation with RSV.

guidelines) contributed the largest PAFs (15.23% [95% CI: 14.56, 15.89], [Table 3](#)).

Discussion

Our study is an expanded and more granular analysis of a wide range of perinatal, socio-demographic, household/environmental factors, and comorbid and congenital conditions, as risk factors for RSV hospitalisation in children <5 years of age and builds on other work in this area.^{16,24,25} In addition to quantifying the effect size of several known and less well recognised medical conditions, we also estimated their contribution at a population level. Our analysis is also a more granular evaluation of risk factors by age group and in Aboriginal children. Using population data, we were able to show that while the risk of hospitalisation for children with some comorbid and congenital conditions is higher than children without these conditions, they had relatively small PAFs, meaning that the proportion of hospitalised cases attributed to that risk

factor at a population level is relatively small. In contrast, some socio-demographic factors such as maternal prenatal smoking, younger pregnancies, and household size made greater contributions at a population level. Both measures are important in guiding decision making for immunisation policy.

Some identified risk factors were common to all age subgroups and in Aboriginal and non-Aboriginal children and are consistent with other studies.^{10,16} Aboriginal and preterm children had an excess risk of hospitalisation and elevated PAFs at every age group and were independent risk factors for all children. In fact, even late preterm birth had a sizeable increased risk for RSV-hospitalisation compared to term children. Prenatal exposure to cigarette smoke impacted both infants and older children. Maternal prenatal smoking affects fetal lung morphology and in turn lung function; prenatal smoking is also a risk factor for preterm birth, leading to pulmonary bronchodysplasia.²⁶ Being born in autumn/winter were a common risk factor to all infants

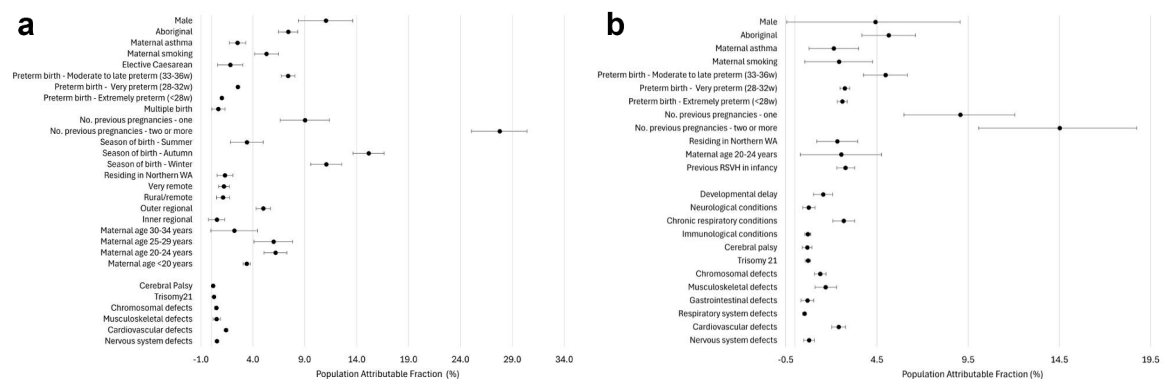


Fig. 3: Population attributable fractions for perinatal and socio-demographic, comorbid, and congenital risk factors for hospitalisation due to RSV in a) infants aged less than 12 months, b) older children aged 12–24 months in Western Australia, 2010–2021. Abbreviation: RSVH: Hospitalisation with RSV.

Department of health criteria	Infants (0–<12 months)				Children (1–<5 years)			
	Index RSVH	Unadjusted HR (95% CI)	Adjusted ^b HR (95% CI)	PAF (95% CI)	Index RSVH	Unadjusted HR (95% CI)	Adjusted ^b HR (95% CI)	PAF (95% CI)
Cardiac								
No	4744	Reference	Reference	Reference	2574	Reference	Reference	Reference
Yes	147	3.71 (3.15, 4.37)	1.11 (0.92, 1.33)	0.29 (–0.21, 0.78)	164	7.14 (5.86, 8.69)	3.71 (2.97, 4.63)	3.08 (2.52, 3.64)
Chronic respiratory								
No	3771	Reference	Reference	Reference	2150	Reference	Reference	Reference
Yes	1120	5.62 (5.26, 6.01)	4.62 (4.29, 4.97)	17.94 (17.57, 18.30)	588	5.24 (4.78, 5.74)	3.32 (2.98, 3.71)	15.23 (14.56, 15.89)
Neuromuscular								
No	4863	Reference	Reference	Reference	2680	Reference	Reference	Reference
Yes	28	3.03 (2.09, 4.40)	1.16 (0.79, 1.68)	0.08 (–0.11, 0.26)	58	11.18 (8.62, 14.50)	3.88 (2.92, 5.14)	1.57 (1.42, 1.72)
Immunological								
No	4881	Reference	Reference	Reference	2721	Reference	Reference	Reference
Yes	10	3.33 (1.79, 6.19)	1.76 (0.94, 3.29)	0.09 (0.02, 0.16)	17	10.60 (6.58, 17.08)	5.55 (3.40, 9.06)	0.47 (0.39, 0.54)
Prematurity								
No	4665	Reference	Reference	Reference	2544	Reference	Reference	Reference
Yes	226	5.05 (4.42, 5.77)	1.66 (1.42, 1.93)	1.83 (1.40, 2.25)	194	8.13 (7.03, 9.41)	4.06 (2.87, 5.74)	4.31 (3.81, 4.81)
Trisomy 21								
No	4872	Reference	Reference	Reference	2713	Reference	Reference	Reference
Yes	19	5.85 (3.73, 9.19)	2.71 (1.70, 4.33)	0.25 (0.18, 0.31)	25	14.59 (9.84, 21.63)	4.57 (2.97, 7.03)	0.73 (0.65, 0.80)
Any condition								
No	3638	Reference	Reference	Reference	2034	Reference	Reference	Reference
Yes	1253	5.40 (5.07, 5.76)	4.88 (4.56, 5.22)	19.88 (19.45, 20.30)	704	8.68 (7.76, 9.70)	7.99 (6.81, 9.38)	20.57 (20.11, 21.03)

Abbreviations: CI: confidence interval; HR: hazard ratio; PAF: Population attributable fraction; RSVH: RSV-hospitalisation. ^aText 2. ^bAdjusted for maternal age, maternal smoking during pregnancy, maternal asthma, mode of delivery, gestational age at birth, plurality, child's gender, Aboriginal status, socioeconomic status, accessibility index, household size, and season of birth.

Table 3: Adjusted hazard ratios and population attributable fractions for comorbid and congenital risk factors identified in the Department of Health criteria^a for hospitalisation due to RSV in children aged less than 5 years, Western Australia, 2010–2021.

but not children aged 12–<24 months and is possibly because of immunological naiveté at the first RSV season.²⁷ Other factors such as younger pregnancy have been reported previously, particularly in Aboriginal mothers.²⁸ Although not all risk factors are modifiable (e.g. male sex and prematurity), and the prevalence of young pregnancies is decreasing,²⁹ other modifiable risk factors such as maternal prenatal smoking still contribute a high PAF. Younger maternal age is possibly an indication of a number of biological and social factors. Younger mothers are more likely to have lower literacy and have less likelihood of or delay in accessing antenatal care, either because of economic disadvantage or inexperience. Younger mothers are less likely to initiate or continue breastfeeding.³⁰ They have higher rates of smoking,²⁹ and a higher risk of pregnancy complications and premature delivery.²⁹ Our analysis has shown that eliminating maternal smoking, a modifiable factor in our analysis, could have a significant impact and reduce RSV-hospitalisation by 15.6% in Aboriginal infants and 3.3% in non-Aboriginal infants.

One risk factor contributing a surprisingly large PAF was household size, particularly in infants. Infants from larger households of two or more children made up a larger proportion of the hospitalised

population compared with firstborns or only children. In a prospective study of RSV household transmission, children aged <5 years were important drivers of RSV transmission in the household.³¹ Health messaging about infection control and hand-washing is actively promoted to parents of preterm children. Non-pharmaceutical interventions such as handwashing and use of sanitisers, in addition to other measures, were effective in halting transmission of RSV and other respiratory viruses during the COVID-19 pandemic.³² These measures should actively be promoted to parents of all infants with multiple children and at childcare centres, regardless of the child's gestational age at birth and any underlying comorbidity.

Medically at-risk children with chronic respiratory conditions defined by DOH guidelines had very high PAFs, as they included all children requiring some form of respiratory support (as per the eligibility criteria) in addition to children identified with a chronic respiratory condition using ICD-10-AM codes, and as such, the criteria were broad. This is in contrast to our inclusion criteria, which did not include children on supplemental oxygen. Regardless, both criteria show that children with chronic respiratory conditions are at higher risk of hospitalisation.

Comorbidities such as immunological and neuromuscular conditions included in the 2024 eligibility criteria did not identify children at higher risk of hospitalisation. While challenging from a logistical, policy perspective, we have shown that some socio-demographic factors make large PAF contributions to the hospitalised RSV child population. Children with some comorbid and congenital conditions, in contrast, while contributing a relatively smaller PAF, may experience a more severe healthcare episode and longer length of stay and the impact of disease on them and on bed-day utilisation and healthcare costs may be considerable. Future work should consider the severity of hospitalisation using measures such as length of stay, admission to ICU and use of supplemental oxygen.

The implementation of the WA DOH nirsevimab immunisation program in 2024 showed that nirsevimab was 84.6% (95% CI: 66.6%, 92.9%) effective against RSV-hospitalisations³³ in WA, similar to other real-world studies,³⁴ and estimated to prevent one third of RSV-hospitalisations across temperate WA in children under two.³⁵ In 2025, for the first time in Australia, a comprehensive hybrid, integrated RSV immunisation program will be available to all pregnant persons and parents of eligible young children. While national guidelines for eligible medically at-risk children are outlined in the Australian Immunisation Handbook,³⁶ there is no consensus on eligibility criteria globally and current international recommendations are highly heterogeneous.^{5,6} Policy settings for eligibility when including medically-at-risk children can be complex and we have shown that some eligibility criteria set by the WA DOH with relatively small PAFs can be amended. Conversely, thought should be given to some socio-demographic factors such as maternal prenatal smoking, younger pregnancies, and household size (proxy for household transmission) that make a larger PAF contribution. Our analysis has shown that despite universal RSV immunisation available in some countries like Australia, which will protect infants in their first year, knowledge of risk factors and PAFs in subsequent years is useful in guiding a high risk program for older children deemed to be at high risk in their second RSV season. Additionally, these results are useful for jurisdictions yet to introduce RSV immunisation programs. As seen in [Figs. 2b and 3b](#), some children continue to have a high risk of RSV-hospitalisation in their second year of life. These children would benefit from second-season immunisation. The high incidence of RSV infection in children <5 years imposes a substantial burden on the healthcare system and emphasises the importance of identifying children at high risk of hospitalisation, information that could assist public health authorities prioritise the allocation of RSV prevention strategies at every RSV season and each age subgroup:

0–<6 months, maternal vaccine & mAb, 6–<12 months, mAb, 12–<24 months, mAb or live attenuated vaccine, 2–<5 years, protein vaccines. Local RSV epidemiology and population structure will also determine public health policy and delivery.

Our study has many strengths, including the use of 10-year statewide population data on all children and all acute care hospitalisations in WA. We also linked pathology testing results to confirm RSV infection, rather than relying on ICD-10-AM coding, known to underestimate the burden of RSV infection.¹⁸ Birth cohort data included a broad range of socio-demographic and perinatal factors. Major congenital anomalies were identified using the WARDA statewide register using BPA codes. The WARDA register is legally mandated and identifies children with congenital anomalies using both passive and active case ascertainment from a number of data sources antenatally up to the age of 6 years.³⁷ We employed a 'lookback approach' to identify comorbid conditions antecedent to RSV-hospitalisation to establish a temporal relationship between exposure and outcome and avoid attributing the condition to sequelae as a result of RSV-hospitalisation, thus minimising confounding.

However, some limitations should be acknowledged. We did not have access to hospital pharmacy data and were unable to identify children on corticosteroid/immunosuppressive therapy, as specified in the DOH's 2024 eligibility criteria for medically at-risk children. We did identify children with heart failure and thus would have captured almost all children on diuretic therapy. Additionally, we did not have information on childcare attendance, known to be a risk factor for respiratory illness.³⁸ We also did not have information on household or passive smoking post-birth, breastfeeding, or a history of severe respiratory infection, although we did include a variable for a previous RSV hospitalisation in infancy for the analysis of children hospitalised in their second and subsequent years. We used a proxy of previous pregnancies to estimate household size, but did not have information on household structure. While palivizumab was licensed for use in high-risk infants in WA during this time period to prevent severe illness by RSV, we did not have access to NeoBase, the neonatal clinical care unit database that records palivizumab administration. However, previous work by our team has shown that compliance was low, with evidence of incomplete dosing.³⁹ We also know that not all admissions are tested for viruses,¹⁸ and testing practices vary according to the child's age, geographical location, season, and the presence of comorbid conditions, with younger children, preterm birth, and residence in a remote location having higher testing rates in WA.²⁰ Older children and children with multiple admissions were more likely to have the condition detected. And finally, we were

unable to assess some medical conditions as we were limited by small numbers, particularly for Aboriginal children.

In conclusion, the landscape for RSV prevention has changed dramatically. RSV immunisation products are already impacting rates of RSV hospitalisation. While there has been great progress in RSV treatment, resources must be delivered to those most at need. In addition to identifying children with comorbid conditions who may be at higher risk of RSV hospitalisation, the importance of socio-demographic risk factors, particularly modifiable factors, should not be undervalued.

Patient and public partnership

The authors would like to acknowledge the ongoing support of the RSV + Community Reference Group at The Kids Research Institute Australia, which includes community members with lived experience of RSV. The RSV + Community Reference Group are a group of 10–15 individuals who have a lived experience of RSV infection. The Group was established in 2022 and meet quarterly, with the purpose of providing a voice in the design and direction of our projects. The forum is also a way of keeping members up to date on the progress of projects. MF is a member of this reference group, an investigator on the project, and a co-author on this publication.

Contributors

MS secured funding for the study, conceptualised the study and contributed to its design, conducted formal data analysis, wrote the original draft of the manuscript, and critically reviewed the manuscript for intellectual content. CCB assisted with clinical input in the design of the study and critically reviewed the manuscript for intellectual content. BWT assisted with the [SFigure 1](#) (map) in the supplement, data curation, and critically reviewed the manuscript for intellectual content. HL assisted with data curation and critically reviewed the manuscript for intellectual content. PCR, KG, and AL secured funding, and critically reviewed the manuscript for intellectual content. CM, DO, JC, and MF assisted with design of the study, critically reviewed the manuscript for intellectual content. HCM conceptualised and secured funding for the study, contributed to the design of the study, and critically reviewed the manuscript for intellectual content. All authors reviewed and approved the final manuscript. MS, BWT, HL and HCM had full access to all the data in the study as stated by appropriate ethics and governance approvals. MS and HCM accessed and verified the data for this study. MS had the final responsibility for the decision to submit. All authors accept responsibility to submit for publication.

Data sharing statement

These linked administrative data are not owned by the authors. Access to the data is approved by data custodians and provided by the WA Data Linkage Branch within the WA Department of Health (<https://www.datalinkageservices.health.wa.gov.au/contact-us>). The use of the data is restricted to named researchers only.

Declaration of interests

HCM has received institutional honoraria for participation in advisory committees sponsored by Merck Sharpe & Dohme (Australia) Pty Ltd, Pfizer, and Sanofi for other work unrelated to this analysis. HCM has also received funding from Sanofi in the form of an external collaboration agreement and investigator-initiated funding from Merck Sharpe

& Dohme (Australia) Pty Ltd for other work unrelated to this analysis. PR has received institutional honoraria from advisory committees or data safety monitoring boards sponsored by GSK, MSD, Sanofi, and Pfizer. PR has been supported for attending meetings/travel from GSK and Sanofi. PR also receives funding from Merck Sharpe & Dohme (Australia) Pty Ltd, Sanofi, and Pfizer. All other authors have no conflicts to declare.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at <https://doi.org/10.1016/j.lanwpc.2025.101654>.

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