Real-world effectiveness of nirsevimab against RSV hospitalisation in infants during a season with low coverage and delayed circulation in Beijing, China: a population-based retrospective cohort study

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Summary

Background Nirsevimab was first deployed in Beijing through a pilot voluntary, self-pay scheme during the 2024–2025 epidemic season, following its approval in China in December 2023. We aimed to evaluate the real-world effectiveness of nirsevimab against RSV-associated lower respiratory tract infection (LRTI) hospitalisation in Beijing, China.

Methods We conducted a population-based retrospective cohort study using linked, individual-level data from the Beijing Immunisation Information System and Hospitalisation Information System. The study population comprised all infants born between April 1, 2024, and March 31, 2025, in 24 designated pilot maternity hospitals. The primary endpoint was RSV-associated LRTI hospitalisation. City-wide virological surveillance was used to define the population-level exposure risk period. Nirsevimab effectiveness was estimated using Bayesian Poisson regression in a propensity score-matched cohort, with three additional models (Firth penalized Poisson, Bayesian Cox, and Firth penalized Cox) as sensitivity analyses.

Findings Among 44,791 eligible infants, 1166 (2.6%) received nirsevimab. In the propensity score-matched cohort (1129 infants per group), the incidence rates of RSV-associated LRTI hospitalisation were 18.8 vs. 2.3 per 1000 person-years in non-recipients and recipients, respectively. Bayesian Poisson regression demonstrated 83.3% effectiveness (95% CrI: 33.3–97.5%; posterior probability: 0.995). Sensitivity analyses yielded consistent estimates (82.8–84.5%). Analyses in the full cohort produced directionally consistent estimates.

Interpretation This first evidence of nirsevimab's effectiveness in China validates its value in a novel geographical and implementation context, supporting its inclusion as a recommended preventive option. Real-time virological surveillance is essential to optimise immunisation timing amid evolving RSV epidemiology.

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Research in context

Evidence before this study

We conducted a comprehensive search of PubMed for studies published in English from inception to March 3, 2026, using the terms "nirsevimab", "real-world effectiveness", "RSV", "hospitalisation", and "infant". A growing body of real-world evidence from high-income countries (including Spain, France, the USA, and Chile) has consistently demonstrated the high effectiveness of nirsevimab (70–90%) against RSV-associated LRTI hospitalisation. These studies, however, were conducted in settings where the product was distributed as part of the national immunisation programmes, with high coverage (up to 97%), and during typical RSV epidemic seasons. A recent systematic review and meta-analysis corroborated these findings and reported a pooled effectiveness of 83%. Notably, no studies to date have evaluated nirsevimab effectiveness under the challenging conditions of low population coverage from a voluntary, self-pay implementation model,a scenario relevant to many middle-income settings during initial rollout, particularly during a markedly delayed and low-intensity epidemic season attributed to post-pandemic viral interference. This leaves a critical evidence gap for many middle-income countries contemplating similar implementation approaches.

Added value of this study

This study provides the first real-world evidence of nirsevimab effectiveness from a middle-income country under challenging conditions. Using Bayesian Poisson regression in a propensity score-matched cohort, a single dose of nirsevimab demonstrated 83.3% effectiveness against RSV-associated LRTI hospitalisation, with three additional models yielding consistent estimates (82.8–84.5%). Methodologically, we pioneered the use of city-wide virological surveillance to define the RSV exposure risk period, ensuring alignment with actual viral circulation during a delayed season—an approach critical for the post-pandemic era of shifting RSV epidemiology. The consistent effectiveness across diverse co-circulating RSV-A and RSV-B lineages confirms the broad protective effect of nirsevimab.

Implications of all the available evidence

The collective evidence, now including our findings from Beijing, supports the high public health value of nirsevimab across diverse geographical and implementation contexts. For policymakers, our results demonstrate that individual-level protection remains high even under suboptimal implementation, reinforcing the need for adequate coverage through immunisation recommendations. Furthermore, the application of virological surveillance highlights its critical role in guiding the timing of immunisation activities, particularly in the post-pandemic era of shifting RSV epidemiology driven by multi-viral interactions.

Introduction

Respiratory syncytial virus (RSV) is the leading cause of lower respiratory tract infection (LRTI) hospitalisation in infants globally,[1–3] making effective prevention a public health priority. In 2023, nirsevimab, a long-acting monoclonal antibody providing at least 5–6 months of protection with a single dose, was approved in multiple jurisdictions.[4] Pivotal clinical trials demonstrated an efficacy of approximately 76.8%–86.5% for nirsevimab against RSV-associated LRTI hospitalisation.[5–8] Subsequent real-world studies across diverse settings in both Northern (e.g., various autonomous communities in Spain, France, Italy, Luxembourg, the United Kingdom, and the United States) and Southern Hemisphere (e.g., Chile and Australia) have consistently confirmed high effectiveness,[9–25] with a recent meta-analysis of 27 studies reporting pooled estimates of 83% against RSV-LRTI hospitalisation and 81% against intensive care unit (ICU) admission in infants.[26] Individual studies consistently report high levels of protection against severe outcomes, with effectiveness against RSV-associated LRTI hospitalisation ranging from 82% to 91% using data from nirsevimab recipients vs. non-recipients in the same year[9,11–13,15,17,18,20,23] and observed RSV-related hospitalisation reduction ranging from 69% to 90% using historical disease burden as a comparator.[10,14,16,22] These studies, conducted during typical RSV seasons with high coverage (up to 97%), affirmed nirsevimab's real-world effectiveness.

However, a critical evidence gap exists: all high-quality real-world evidence to date originates from settings with high coverage and predictable typical epidemiological seasons. In many middle-income countries, innovative biologics like nirsevimab are initially introduced through voluntary, self-pay schemes, resulting in substantially low and heterogeneous coverage. Furthermore, the post-pandemic era has seen increasingly atypical RSV circulation patterns, including delayed seasons and varied epidemic intensity.[27–29] Whether nirsevimab demonstrates similar effectiveness under these challenging conditions—low coverage coupled with irregular RSV epidemics—remains unknown, yet this question is crucial for informing implementation strategies in resource-constrained settings.

The RSV monoclonal antibody (mAb) pilot campaign conducted in Beijing, China, during the 2024–2025 season provides a unique natural experiment opportunity to address this evidence gap. Implemented as a biological product with a voluntary, self-pay scheme in the existing immunisation framework, the pilot initiative achieved overall low population coverage in the first year of introduction despite efforts to improve accessibility. Concurrently, Beijing experienced an atypical RSV season characterised by substantially reduced epidemic intensity and a delayed peak relative to the traditional October–March pattern.[30] We conducted this population-based cohort study to evaluate the effectiveness of nirsevimab against RSV-associated LRTI hospitalisation in Beijing during the 2024–2025 season. Recognizing these challenging conditions, virological surveillance was employed to define the epidemic period to ensure accurate assessment of protection during actual viral circulation.

Methods

Study design and population

We conducted a population-based retrospective cohort study to evaluate the real-world effectiveness of nirsevimab against RSV-associated LRTI hospitalisation. Using the Beijing Immunisation Information System (BIIS), we constructed a birth cohort with comprehensive demographic data (birth date, birth weight, and gestational age) and immunisation records (including nirsevimab administration with dates and locations, and other vaccinations). This system enabled the identification of nirsevimab recipients and non-recipients. Through linkage with the Beijing Hospitalisation Information System (BHIS), we ascertained all RSV-associated LRTI hospitalisations, including clinical details such as admission and discharge dates, diagnoses, and ICU admissions. We defined the exposure risk period using city-wide RSV virological surveillance data to ensure precise alignment with the actual epidemic season.

The study population comprised all infants born between April 2024 and March 2025 at 24 designated maternity hospitals that participated in Beijing's pilot RSV mAb administration campaign. These hospitals were purposively selected by the local Municipal Health Commission based on three criteria: (1) annual delivery volume, (2) geographic distribution across urban, suburban, and rural districts, and (3) capacity to implement the novel administration protocol. This selection strategy was designed to ensure representativeness of the pilot network. Infants were excluded from the analysis if they had missing identification information (necessary for accurate data linkage), received nirsevimab outside the designated campaign period, or had an RSV-related hospitalisation history.

Administration strategy

The campaign targeted all infants entering or experiencing their first RSV season, including both term and preterm infants. Nirsevimab was administered as a single intramuscular injection with weight-based dosing: 50 mg for infants weighing less than 5 kg and 100 mg for those weighing 5 kg or more. The campaign ran from October 1, 2024, to March 31, 2025, aligned with Beijing's typical RSV epidemic season. Two administration pathways were established: birth-dose administration at pilot maternity hospitals and post-discharge administration at pilot community health centre vaccination clinics. For infants born between April and September 2024, administration was scheduled at either neonatal departments of pilot hospitals or community vaccination clinics. For those born between October 2024 and March 2025, administration was planned before maternity hospital discharge, with community vaccination clinics serving as catch-up sites for those who missed the birth dose.

Surveillance-informed exposure risk period

The Beijing Acute Respiratory Infection Multi-pathogen Surveillance System defined the epidemic season, serving as the exposure risk period for this study. Operating continuously through 19 sentinel hospitals, the system monitors 22 respiratory pathogens, including RSV, among inpatients meeting the severe acute respiratory infection (SARI) case definition: acute onset, fever$\geq$38 °C, cough, and illness duration $\leq$10 days. For SARI cases, upper and lower respiratory specimens (e.g., nasopharyngeal swabs, sputum, bronchoalveolar lavage fluid) are collected within 7 days of onset and tested by multiplex nucleic acid assay within 12 h. RSV-positive samples with Ct $<$ 30 were sequenced to characterize circulating strains. Season onset was defined as the date of sustained increase in RSV positivity, accounting for RSV's estimated one-week incubation period; Season end was defined as the date when positivity became undetectable. As a sensitivity analysis to assess robustness to the choice of surveillance indicator, we also defined an alternative exposure risk period based on RSV positivity among influenza-like illness (ILI) cases in children aged 0–4 years, using the same definition criteria (see Supplementary Appendix).

For nirsevimab recipients vaccinated before the surveillance-defined season start date, follow-up commenced on the season start date; for those administered during the season, follow-up began on the date of administration. Among non-recipients, follow-up started on either the season start date (for infants born before) or the birth date (for those born during the season). Follow-up concluded at the earliest occurrence of: first RSV-LRTI hospitalisation, the surveillance-defined season end, six months post administration (recipients) or follow-up initiation (non-recipients), or death.

Outcome definition

Outcome data for this study were obtained from the BHIS, an electronic platform managed by the Municipal Health Commission's Information Center. The system aggregates standardized inpatient demographic and discharge records from all tertiary and secondary hospitals, as well as over 50% of primary care facilities across the city. Based on official statistics, BHIS captured approximately 94% of all hospital admissions in Beijing during 2024–2025, ensuring near-complete coverage of hospitalisations for the city's resident population. Data quality is maintained through automated validation rules at the point of entry, standardized coding protocols (ICD-10), and regular audits conducted by the Municipal Health Commission.

We defined the primary outcome as the first episode of RSV-associated LRTI requiring hospitalisation. All-cause LRTI hospitalisations were initially identified from the BHIS using a broad set of ICD-10 codes: J12–J18 (pneumonia), J20–J22 (acute bronchitis, acute bronchiolitis, and unspecified acute lower respiratory infection), and B34.803 (respiratory syncytial virus infection). Case identification then required laboratory confirmation of RSV, which was documented in the hospitalisation records as a positive PCR or antigen test. Only laboratory-confirmed cases were included in the final outcome analysis. The secondary outcome, severe RSV-associated LRTI, was defined as cases requiring admission to a neonatal or paediatric ICU.

Statistical analysis

Participants were classified as nirsevimab recipients or non-recipients. Categorical variables were compared using χ^2 or Fisher's exact tests and presented as frequencies (%). Continuous variables were assessed for normality; normally distributed variables were summarized as mean ± standard deviation (SD) and compared using Student's t-test, while non-normally distributed variables were presented as median and interquartile range (IQR) and compared using the Wilcoxon rank-sum test. Given the small number of events, we used complementary statistical approaches to estimate nirsevimab effectiveness. For all models, effectiveness against RSV-associated LRTI hospitalisation was calculated as (1—effect estimate) × 100% with 95% confidence or credible intervals. Incidence rates (events per 1000 person-years) and incidence rate differences were calculated to provide absolute effect measures.

Primary analysis

To address baseline imbalances, we performed 1:1 nearest-neighbor propensity score matching (caliper width 0.1) without replacement, incorporating age (<3, 3–6, >6 months), sex, low birth weight (<2.5 kg), preterm birth (<37 weeks), pentavalent vaccine and 13-valent pneumococcal conjugate vaccine (PCV13) vaccination status (as proxies for willingness to pay). Covariate balance was assessed using standardized mean differences (<0.1 indicating adequate balance).

In the matched cohort, we used Bayesian Poisson regression with weakly informative priors as the primary approach to estimate nirsevimab effectiveness. Specifically, the number of RSV-associated LRTI hospitalisations for infant i was modelled as a Poisson distribution: $y_i \sim \text{Poisson}\ (\lambda_i)$, with the log rate expressed as: $\log\ (\lambda_i) = \beta_0 + \beta_1 \times nirsevimab_i + \text{offset}\ (\log\ t_i)$, where t_i is the person-years of follow-up. Weakly informative normal priors were assigned to all regression coefficients: $\beta \sim \text{Normal}\ (0, 2.5)$ on the log-risk scale. We reported the posterior median relative risk (RR), 95% credible intervals (CrIs), and the posterior probability of effectiveness (RR < 1). Three pre-specified sensitivity analyses assessed consistency: (1) Firth penalized Poisson regression, (2) Bayesian Cox regression, and (3) Firth penalized Cox regression.

Secondary analyses

In the full (pre-PSM) cohort, we applied the same analytical framework as the primary analyses, using Bayesian Poisson regression with the three additional models (Firth penalized Poisson, Bayesian Cox, and Firth penalized Cox) as sensitivity analyses. For infants with missing birth weight or gestational age, median imputation was applied in the full cohort analyses.

For the severe outcome of ICU admission, incidence rates (events per 1000 person-years) and incidence rate differences were calculated to provide absolute effect measures.

All analyses were performed using R 4.2.0, with a two-sided significance level of $\alpha = 0.05$ for frequentist analyses. For Bayesian analyses, posterior probabilities >0.95 were considered indicative of evidence for a protective effect.

Ethics approval

Ethical approval for this study was obtained from the Ethics Committee of Beijing Center for Disease Prevention and Control (approval number: BJCDC2025032). The requirement for informed consent was waived due to the use of anonymised retrospective data.

Role of the funding source

The funders of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Study population and baseline characteristics

The study initially identified 49,962 infants born in 24 pilot hospitals between April 1, 2024, and March 31, 2025. After applying predefined exclusion criteria, namely excluding 4906 infants with missing identification information, 253 infants who received nirsevimab outside the campaign period, and 12 infants who had an RSV-LRTI hospitalisation prior to the exposure risk period, the final analytical cohort comprised 44,791 infants. Of these, 1166 infants (2.6%) received nirsevimab, while 43,625 (97.4%) did not (Fig. 1).

The 24 pilot hospitals accounted for 36.8% of all live births in Beijing during the study period. Comparisons with non-pilot hospitals showed no significant differences in geographic distribution (*P* = 0.922) and hospital type (*P* = 0.067). Birth weight and gestational age distributions were broadly comparable between groups: low birth weight (<2.5 kg) occurred in 6.1% of pilot vs. 5.9% of non-pilot infants (*P* = 0.014); preterm birth (<37 weeks) in 6.9% vs. 6.7% (*P* = 0.071) (Table 1).

Overall, 92.6% of infants were term (≥37 weeks) and 93.7% had normal birth weight (≥2.5 kg). Baseline characteristics differed significantly between groups before matching (Table 2). Recipients were younger

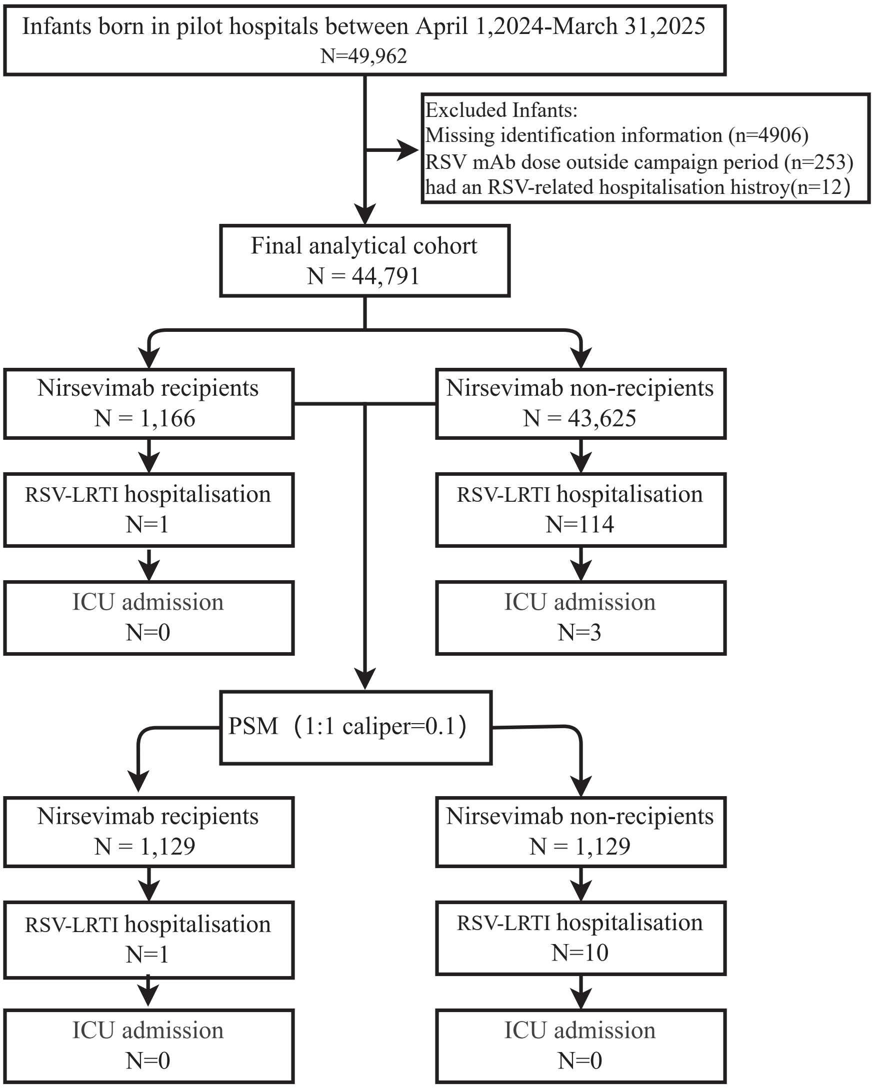

Fig. 1: **Flowchart of study population enrollment and outcomes.** Infants born in pilot hospitals between April 1, 2024 and March 31, 2025, were included. After exclusions, the final cohort comprised 44,791 infants. Propensity score matching (1:1, caliper = 0.1) was applied to balance baseline characteristics between nirsevimab recipients and non-recipients. RSV = respiratory syncytial virus. LRTI = lower respiratory tract infection. ICU = intensive care unit.

Characteristics	Pilot hospitals (n = 24)	Non-pilot hospitals (n = 87)	Total (n = 111)	P-value
Number of hospitals	24 (21.6)	87 (78.4)	111 (100)	
Number of infants	44,791 (36.8)	76,759 (63.2)	121,550 (100)	
Region[a]				0.922
Urban	16 (66.7)	56 (64.4)	72 (64.9)	
Suburban	6 (25.0)	25 (28.7)	31 (27.9)	
Rural	2 (8.3)	6 (6.9)	8 (7.2)	
Hospital type[b]				0.067
General	14 (58.3)	69 (79.3)	83 (74.8)	
Specialty	10 (41.7)	18 (20.7)	28 (25.2)	
Weight at birth[c], kilograms				
<2.5	2733 (6.1)	4527 (5.9)	7260 (6.0)	0.014
≥2.5	41,959 (93.7)	72,002 (93.8)	113,961 (93.7)	
Missing	99 (0.2)	230 (0.3)	329 (0.3)	
Gestational age at birth[d], weeks				
<37	3117 (6.9)	5139 (6.7)	8256 (6.8)	0.071
≥37	41,470 (92.6)	71,313 (92.9)	112,783 (92.8)	
Missing	204 (0.5)	307 (0.4)	511 (0.4)	

Data are presented as n (%). Percentages for "Number of hospitals" and "Number of infants" are row percentages showing distribution across hospital groups; all other variables are column percentages for characteristics within each group. *P* values were calculated using the χ^2 test. [a]Region: Urban (central city districts); Suburban (peri-urban areas); Rural (outer county districts). [b]Hospital type: General (multispecialty); Specialty (e.g., obstetrics, pediatrics, traditional Chinese medicine). [c]Weight at birth: Low birth weight was defined as < 2.5 kg. [d]Gestational age at birth: Preterm was defined as < 37 weeks.

***Table 1:* Characteristics of RSV mAb pilot vs. non-pilot hospitals.**

(<3 months: 4.8% vs. 10.1%; >6 months: 60.5% vs. 65.3%; $P < 0.001$) and had a higher prevalence of low birth weight (13.8% vs. 5.9%) and preterm birth (15.0% vs. 6.7%, both $P < 0.001$). Recipients also had higher coverage of pentavalent vaccine (92.7% vs. 63.5%) and PCV13 (87.2% vs. 54.5%, both $P < 0.001$). After matching (1129 per group), baseline characteristics were well balanced (all standardized mean differences <0.1, $P \geq 0.165$).

Surveillance-informed exposure risk period

Virological surveillance revealed an atypical RSV epidemic pattern during the 2024–2025 season (Fig. 2a). Among SARI cases aged 0–4 years, RSV positivity began rising in mid-December, reaching 7.7% by December 23, 2024. After accounting for a one-week incubation period, the epidemic onset was defined as December 16, 2024. Positivity peaked at 52.9%, then declined to 6.7% by June 15, 2025, and became undetectable thereafter. The epidemic season was therefore defined as December 16, 2024, to June 15, 2025, serving as the exposure risk period for this study. Cumulative doses increased progressively throughout the study period (Fig. 2b). Of the 1166 recipients, 565 (48.5%) received nirsevimab before the season start (December 16, 2024) and 601 (51.5%) during the season. The rise in cumulative RSV cases accelerated in late December 2024, coinciding with increasing RSV activity detected through SARI surveillance.

Molecular characterization of RSV isolates revealed a near-equal distribution between RSV-A (52.9%, 18/34) and RSV-B (47.1%, 16/34), indicating concurrent circulation of both genotypes during the study period. Within the RSV-A genotype, lineages A.D.5.2 (33.3%) and A.D.3 (27.8%) were predominant, while several minor lineages were also detected, including A.D.3.12 (5.6%), A.D.1.4 (11.1%), A.D.1.5 (11.1%), and A.D.1.6 (11.1%), reflecting substantial genetic diversity. By contrast, the RSV-B genotype showed less diversity, with lineage B.D.E.1 accounting for 87.5% of cases and lineage B.D.4.1.1 comprising the remaining 12.5% (Fig. 3).

Effectiveness of nirsevimab

One RSV-associated LRTI hospitalisation occurred among recipients vs. 114 among non-recipients. Among 115 confirmed cases, 112 (97.4%) were PCR-confirmed and 3 (2.6%) antigen-confirmed.

In the PSM cohort (1129 per group), Bayesian Poisson regression estimated effectiveness at 83.3% (95% CrI: 33.3–97.5; posterior probability: 0.995). Three sensitivity analyses yielded consistent estimates: Firth penalized Poisson: 82.8% (95% CI: 4.7–96.9; $P = 0.044$); Bayesian Cox: 84.5% (95% CrI: 32.3–97.9; posterior probability 0.996); Firth penalized Cox: 83.5% (95% CI: 29.5–98.2; $P = 0.012$). Full cohort analyses produced directionally consistent but less precise estimates (Table 3).

In the PSM cohort, incidence rates of RSV-associated LRTI hospitalisation were 18.8 per 1000 person-years in non-recipients (10/532) vs. 2.3 per 1000 person-years in recipients (1/442), yielding a rate difference of 16.5 per 1000 person-years. For ICU admission, no events occurred in the PSM cohort. In the full

Characteristics	Nirsevimab Recipients	Nirsevimab Non-recipients	Overall	*P*-value
Before PSM	1166	43,625	44,791	
Age, months				<0.001
<3	56 (4.8)	4425 (10.1)	4481 (10.0)	
3–6	404 (34.7)	10,713 (24.6)	11,117 (24.8)	
>6	706 (60.5)	28,487 (65.3)	29,193 (65.2)	
Sex				0.334
Male	590 (50.6)	22,718 (52.1)	23,308 (52.0)	
Female	576 (49.4)	20,907 (47.9)	21,483 (48.0)	
Weight at birth[a], kilograms				<0.001
<2.5	161 (13.8)	2572 (5.9)	2733 (6.1)	
≥2.5	1001 (85.9)	40,958 (93.9)	41,959 (93.7)	
Missing	4 (0.3)	95 (0.2)	99 (0.2)	
Gestational age at birth[b], weeks				<0.001
<37	175 (15.0)	2942 (6.7)	3117 (6.9)	
≥37	985 (84.5)	40,485 (92.8)	41,470 (92.6)	
Missing	6 (0.5)	198 (0.5)	204 (0.5)	
Pentavalent vaccine receipt	1081 (92.7)	27,718 (63.5)	28,799 (64.3)	<0.001
PCV13 vaccine receipt	1017 (87.2)	23,763 (54.5)	24,780 (55.3)	<0.001
After PSM	1129	1129	2258	
Age, months				1.000
<3	56 (5.0)	56 (5.0)	112 (5.0)	
3–6	367 (32.5)	367 (32.5)	734 (32.5)	
>6	706 (62.5)	706 (62.5)	1412 (62.5)	
Sex				0.165
Male	569 (50.4)	603 (53.4)	1172 (51.9)	
Female	560 (49.6)	526 (46.6)	1086 (48.1)	
Weight at birth[a], kilograms				1.000
<2.5	159 (14.1)	159 (14.1)	318 (14.1)	
≥2.5	970 (85.9)	970 (85.9)	1940 (85.9)	
Gestational age at birth[b], weeks				1.000
<37	172 (15.2)	172 (15.2)	344 (15.2)	
≥37	957 (84.8)	957 (84.8)	1914 (84.8)	
Pentavalent vaccine receipt	1046 (92.6)	1046 (92.6)	2092 (92.6)	1.000
PCV13 vaccine receipt	984 (87.2)	984 (87.2)	1968 (87.2)	1.000

Data are presented as n (%). *P* values were calculated using the χ^2 test for all categorical comparisons. [a]Weight at birth: Low birth weight was defined as <2.5 kg. [b]Gestational age at birth: preterm birth was as <37 weeks of gestational age.

Table 2: **Characteristics of the study population.**

cohort, no events occurred among recipients (0/1166) vs. three among non-recipients (3/43,625), corresponding to a rate difference of 0.07 per 1000 person-years.

Discussion

In Beijing's inaugural nirsevimab pilot scheme, implemented through a voluntary, self-pay model, a single dose provided substantial protection against RSV-associated LRTI hospitalisation in infants. Our findings, demonstrating substantial protection despite low coverage and a markedly delayed RSV epidemic, align with effectiveness estimates from high-coverage universal immunisation programmes while providing the first evidence from China and validating nirsevimab's value in a novel geographical and implementation context.

A key methodological strength of this study was the use of city-wide virological surveillance data to precisely define the RSV exposure risk period. This approach specifically addressed the challenge of post-pandemic RSV seasonality shifts, as exemplified by a 4-month delay in the RSV epidemic peak in Southern France[31] and a 1.7-fold increase in paediatric hospitalisation during an early, intense epidemic in Denmark in 2022.[32] This surveillance-guided approach ensured accurate alignment of the at-risk follow-up time with the actual period of high RSV transmission.

Our study provides valuable biological insights through the genetic characterization of RSV strains from SARI cases. We identified concurrent circulation of diverse RSV-A lineages (predominantly A.D.5.2 and A.D.3) and RSV-B lineages (predominantly B.D.E.1), indicating substantial genotypic diversity during the

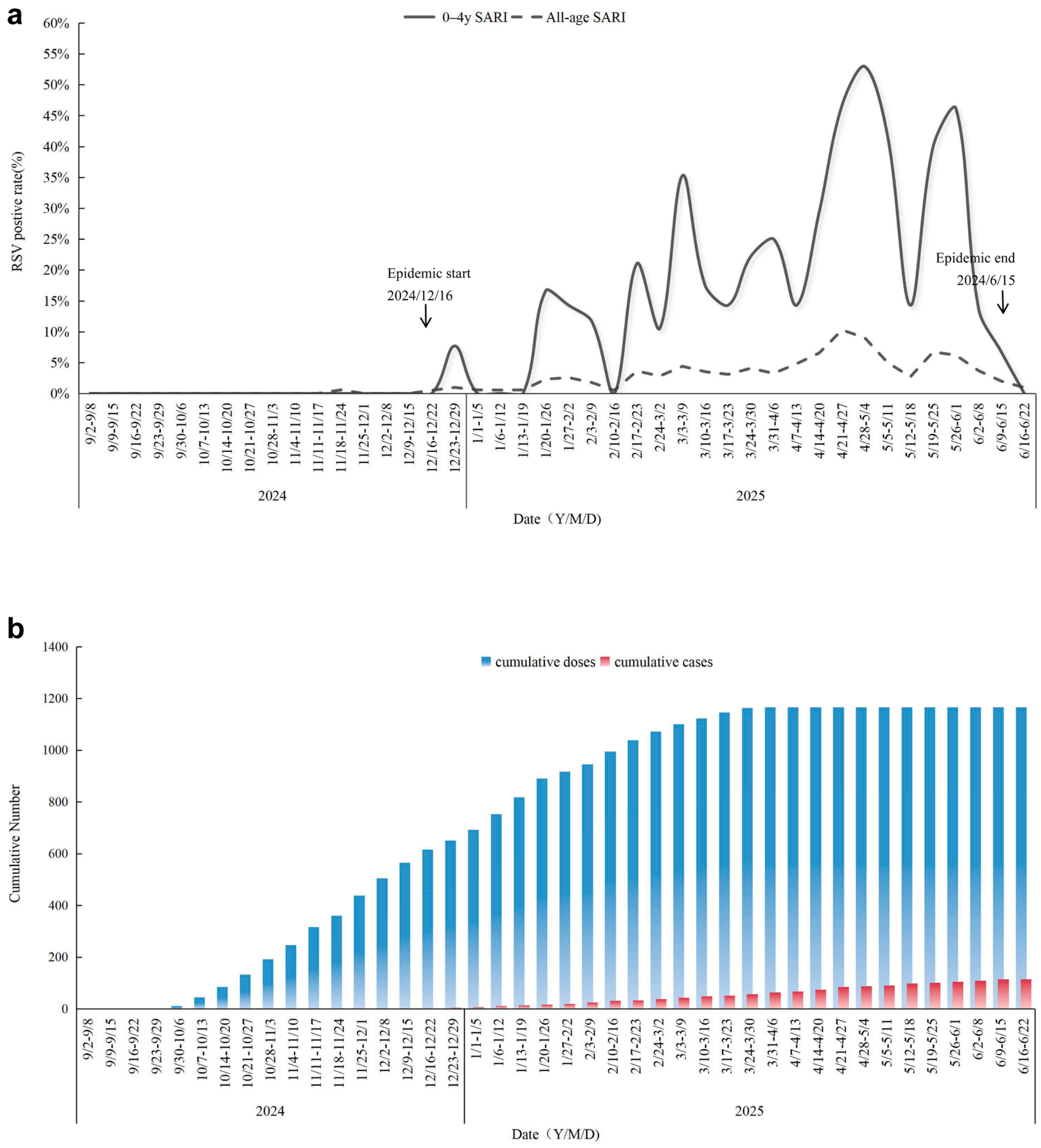

Fig. 2: **RSV activity, cumulative cases, and nirsevimab administration in Beijing, 2024–2025 season.** (a) Weekly RSV positivity rate (%) among SARI cases from the Beijing Multi-pathogen Surveillance System. The arrow indicates the virologically defined RSV season (December 16, 2024–June 15, 2025), used as the exposure risk period. Severe acute respiratory infection = SARI. (b) Weekly cumulative nirsevimab doses administered from campaign initiation (October 1, 2024) overlaid with weekly cumulative RSV-associated LRTI hospitalisations.

study period. This pattern is consistent with contemporary genomic surveillance reports from other regions.[33,34] The high effectiveness observed against this heterogeneous viral background provides encouraging evidence for nirsevimab's broad protective effect across circulating lineages.

We defined the exposure risk period to align with the empirically determined RSV epidemic season (approximately 6 months), rather than using fixed post-administration follow-up (e.g., 150 days in MELODY).[35] This season-based design captures protection during peak transmission, the most relevant context for real-world effectiveness. Using SARI-based surveillance ensured alignment with our hospitalisation outcome. The observed effectiveness of 82.8–84.5% over this period aligns with the 80–90% protection reported in

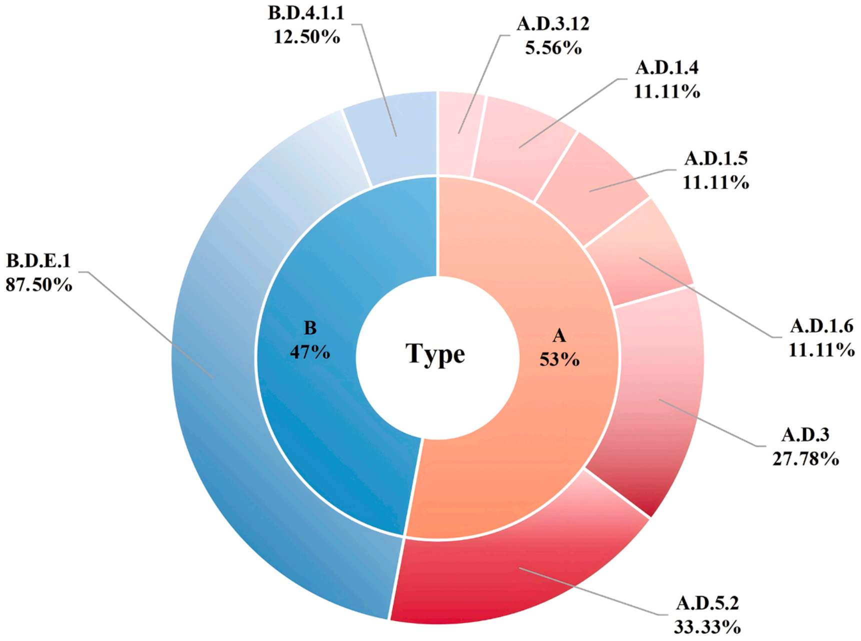

Fig. 3: **Genotype distribution of RSV isolates from SARI cases in Beijing, 2024–2025 season.** The pie chart illustrates the genotype distribution from sequencing analysis of RSV-positive SARI cases.

clinical trials,[4–8,26,36] as well as real-world studies from high-income settings, and with the pooled effectiveness of 83% (95% CI: 77–87) from a recent meta-analysis of 32 real-world studies,[26] validating nirsevimab's broad effectiveness across diverse populations.

Given sparse event data and baseline imbalances, we selected Bayesian Poisson regression with weakly informative priors as the primary analytical approach. This method does not rely on the proportional hazards assumption, provides stable estimates under rare events, and yields posterior probabilities quantifying evidence strength. Three sensitivity analyses—Firth penalized Poisson, Bayesian Cox, and Firth penalized Cox—addressed rare-event bias and time-to-event dynamics. The consistent effectiveness estimates across all four models (82.8–84.5%) in the PSM cohort and

Analysis approach	Events/person-years (Rate per 1000 PY)		Relative risk/hazard ratio (95% CI/CrI)	Effectiveness % (95% CI/CrI)	*P*-value/posterior Prob.
	Non-recipients	Recipients			
Primary analysis (PSM cohort)					
Bayesian Poisson regression	10/532 (18.8)	1/442 (2.3)	0.167 (0.025, 0.667)[a]	83.3 (33.3, 97.5)[a]	0.995[b]
Sensitivity analysis (PSM cohort)					
Firth penalized Poisson regression	10/532 (18.8)	1/442 (2.3)	0.172 (0.031, 0.953)	82.8 (4.7, 96.9)	0.044
Bayesian Cox regression			0.155 (0.021, 0.677)[a]	84.5 (32.3, 97.9)[a]	0.996[b]
Firth penalized Cox regression			0.165 (0.018, 0.705)	83.5 (29.5, 98.2)	0.012
Secondary analysis (Full cohort)					
Bayesian Poisson regression	114/20,035 (5.7)	1/455 (2.2)	0.217 (0.02, 0.875)[a]	78.3 (12.5, 98.0)[a]	0.983[b]
Sensitivity analysis (Full cohort)					
Firth penalized Poisson regression	114/20,035 (5.7)	1/455 (2.2)	0.287 (0.06, 1.385)	71.3 (−38.5, 94.0)	0.120
Bayesian Cox regression			0.163 (0.017, 0.734)[a]	83.7 (26.6, 98.3)[a]	0.992[b]
Firth penalized Cox regression			0.566 (0.064, 2.075)	43.4 (−107.5, 93.6)	0.450

Rates are per 1000 person-years. The propensity score-matched (PSM) cohort was created using 1:1 nearest-neighbor matching (caliper = 0.1), achieving balance on age, sex, low birth weight, preterm birth, pentavalent vaccine, and PCV13 receipt. For each cohort, we present four models: Poisson (RR) and Cox (HR), each with Firth penalized and Bayesian approaches. In the PSM cohort, Bayesian Poisson was the pre-specified primary analysis; the other three models were sensitivity analyses. Analyses in the full cohort were secondary. [a]Posterior median with 95% credible interval (CrI). [b]Posterior probability of effectiveness (RR or HR < 1). PY = person-years; CI = confidence interval.

Table 3: **Effectiveness of nirsevimab against RSV-associated LRTI hospitalisation.**

Bayesian posterior probabilities exceeding 0.99 provide strong evidence for a protective effect despite wide credible intervals, supporting the robustness of our conclusions.

Our findings have two key policy implications. First, the substantial protection observed despite low coverage (2.6%) supports nirsevimab's inclusion as a recommended preventive option in national immunisation guidelines. While universal programmes with high coverage (up to 97%) have achieved >80% reductions in RSV hospitalisations in countries like Spain, Chile, and Luxembourg,[10,16,36] our study confirms that individual-level benefits are preserved even during low-coverage initial rollout. Second, our experience highlights the critical role of real-time virological surveillance in guiding immunisation timing. Although WHO recommends administration shortly before the RSV season,[37] accurately predicting epidemic onset remains challenging amid shifting post-pandemic patterns. Our findings support initiating campaigns based on historical timing while using surveillance data to determine when to conclude, ensuring peak antibody titres coincide with transmission risk, a strategy consistent with a French study attributing higher effectiveness to close temporal alignment with the epidemic peak.[17]

The interpretation of our findings should be contextualised within several limitations. **First**, the small number of outcome events, particularly the single event in the nirsevimab group, limited the statistical power to detect differences, and resulted in the reduced precision of our effectiveness estimates, as reflected by the wide confidence/credible intervals across all models. In the primary analysis of the PSM cohort, effectiveness estimates from four complementary models ranged from 82.8% to 84.5%, with 95% confidence/credible intervals spanning approximately 4.7% to 98.2%. These wide intervals indicate that the true effectiveness could range from modest to very high. Therefore, while all models consistently point toward high protection, these results should be interpreted with caution, given the imprecision of the estimates. For the severe outcome of ICU admission, the extreme sparsity of events precluded reliable estimation of relative effect measures. The absence of ICU events among recipients is clinically reassuring but does not permit formal effectiveness estimation for this endpoint; larger studies are needed to quantify this endpoint precisely. **Second**, regarding the generalizability of our effectiveness estimate, it is important to note that our study cohort was demographically representative of the natural birth population in Beijing, and the majority of nirsevimab recipients were term and normal birth weight infants. Nevertheless, precision for subgroup-specific estimates among infants with potential health conditions (e.g., preterm infants) is limited due to a smaller sample size. Future studies with larger samples are needed to confirm effectiveness across subgroups. **Third**, as an observational study of a voluntary, self-pay intervention, our findings are susceptible to healthy user and affordability bias. Nirsevimab recipients had higher coverage of other self-pay vaccines (e.g., pentavalent vaccine and PCV13), suggesting differences in health-seeking behavior and socioeconomic status that could confound the observed association. We addressed this through adjustment for these vaccines as proxies for health investment propensity and through propensity score matching to balance measured confounders. However, residual confounding from unmeasured socioeconomic factors (e.g., income, education, and healthcare access) remains possible. Future studies incorporating direct measures of socioeconomic status are warranted. **Fourth**, as an evaluation conducted during the inaugural season of nirsevimab implementation, several important questions remain unresolved. These include strain-specific effectiveness, middle and long-term protective effects such as reducing the risk of recurrent wheezing and asthma, the duration of protection beyond 6 months, and the potential influence of annual variations in viral circulation and immune escape. Future studies with enhanced sample sizes, extended follow-up duration, and expanded genomic and epidemiological surveillance are warranted to address these critical knowledge gaps.

Our study provides preliminary but consistent evidence that nirsevimab is highly effective in preventing severe RSV disease in Chinese infants, with estimates aligned with those from high-coverage settings. These findings provide supportive evidence for broader implementation of nirsevimab across China. Future research should evaluate long-term health impact and population-level effects under high-coverage scenarios. As a self-pay intervention, its impact may be limited by socioeconomic disparities. To achieve equitable protection, future policies should consider strategies to improve affordability and access.

Contributors

PY, LDS, and JL conceived the study and secured funding. PY, LDS, QYW, and MNG led and coordinated the project. JL and ZQC directed the data consolidation and linkage from the Beijing Immunisation Information System (BIIS) and Beijing Hospitalisation Information System (BHIS). HX, YS, DW, and ZMF were responsible for the acquisition and validation of surveillance data from the Beijing Acute Respiratory Infection Multi-pathogen Surveillance System. JL and LW were responsible for data cleaning, statistical analyses, and generating tables and figures. JL drafted the original manuscript. JYL, PG, and RY have accessed and verified the underlying data. PY, LDS, QYW, MNG, and FL contributed to the study design, interpretation of results, critically revised the manuscript, and approved the final version. All authors had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Data sharing statement

The individual, de-identified participant data that underlie the results reported in this article will be made available following article publication. The study protocol and statistical analysis plan will also be shared. Data will be available to researchers who provide a methodologically sound proposal for use in achieving the goals of the approved proposal. Proposals should be directed to the corresponding author (corresponding author email); to gain access, data requestors will need to sign a data access agreement.

Declaration of interests

We declare no competing interests.

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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.2026.101861.

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