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Cost-effectiveness analysis of nirsevimab for prevention of respiratory syncytial virus disease among infants in Shanghai, China: A modeling study

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ABSTRACT

Chinese authority approved nirsevimab to prevent respiratory syncytial virus (RSV) in January 2024. We aimed to assess the cost-effectiveness of nirsevimab immunization among infants in Shanghai. A decision-tree Markov model was developed to compare two strategies – year-round and seasonal immunization – with nonintervention, from a societal perspective, using RSV-associated disease burden and demographic data. Twelve monthly birth cohorts were followed through 24 one-month Markov cycles. Two scenarios of nirsevimab efficacy were considered: short-duration and long-duration. The incremental cost-effectiveness ratio (ICER) (incremental costs per quality-adjusted life year [QALY] gained) was calculated and the willingness-to-pay (WTP) threshold was set at gross domestic product (GDP) per capita. Sensitivity analysis was performed to evaluate the uncertainty. Both immunization strategies demonstrated cost-effectiveness across efficacy scenarios, with seasonal approach yielding lower ICERs than the year-round approach. The cost-effectiveness of the seasonal approach was influenced by the timing of its administration. Nirsevimab immunization may be an economically favorable strategy for infant RSV prevention in Shanghai. The optimal program timing of seasonal immunization requires further investigation to maximize public health impact.

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Introduction

Respiratory syncytial virus (RSV) represents a significant cause of acute lower respiratory infections (ALRI) among infants and young children. In 2019, it was estimated that 33.0 million cases of RSV-ALRI occurred globally in children under five years of age, with approximately 10% of these cases reported in China.[1] Immunization is widely recognized as one of the most effective public health strategies. While earlier attempts to develop an RSV vaccine were marred by adverse outcomes, such as enhanced RSV disease leading to fatalities in two toddlers,[2] recent advancements in RSV prophylactic interventions have demonstrated significant potential in reducing RSV-related morbidity and mortality.

Palivizumab, a humanized monoclonal antibody (mAb), was approved by the United States Food and Drug Administration (FDA) in 1998 for the prevention of RSV infections in infants.[3] However, its limited duration of protection (approximately one month) and high cost restricted its use primarily to high-risk infants, such as those with chronic lung disease.[3] In 2023, FDA approved nirsevimab, a novel mAb, which demonstrated an efficacy of 79.5% against medically attended RSV lower respiratory tract infections over a 150-day period following administration.[4] Notably, nirsevimab was priced significantly lower than palivizumab (US$ 520 vs. US$ 1927), making it more accessible option for broader infant immunization. In January 2024, the regulatory authorities in China approved nirsevimab,[5] and by July 2024, it has been authorized in 48 countries and territories globally.[6]

Cost-effectiveness analysis has played a critical role in shaping recommendations for the use of nirsevimab. Studies conducted in countries such as the United Kingdom, Canada, Kenya, and South Africa have highlighted its economic and clinical value under diverse healthcare settings.[7–9] In China, Liu et al. conducted a cost-effectiveness analysis of nirsevimab immunization across eight cities prior to its official approval and implementation.[10] The study concluded that nirsevimab could be cost-effective under appropriate pricing conditions. However, the evolving landscape – marked by the formal implementation of nirsevimab in several Chinese cities, including Beijing and Shanghai, since September 2024—and the availability of updated data on RSV-related economic burden and health utilities in children highlight the necessity of revisiting and localizing the evidence.[11]

This study aimed to assess the cost-effectiveness of nirsevimab immunization among infants in Shanghai, a densely

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populated metropolitan and a leading economic hub in China. Given the demographic and healthcare dynamics of Shanghai, localized evidence is essential to guide immunization strategies and inform the selection of optimal policies. The findings of this study are expected to provide critical insights into the development and implementation of related health policies aimed at mitigating the burden of RSV in Shanghai and beyond.

Method

Study design and model overview

We assessed the cost-effectiveness of administering nirsevimab to newborns in comparison to no intervention using a decision-tree Markov model from the societal perspective. The analysis considered 12 birth cohorts of newborns, stratified by month of birth, with each cohort monitored monthly over the first 24 months of life (Figure 1(a)).

The model was developed based on the framework used in a previous study.[10] The Markov model comprised four states: susceptibility, mAb-induced immunity, infection-induced immunity, and death (Figure 1(b)). Newborns were initially considered susceptible to RSV infection. The model captured RSV-ALRI associated medical events after RSV infection, including three potential clinical outcomes: outpatient visits, hospitalizations, and deaths. Infants receiving nirsevimab (mAb-induced immunity) or experiencing RSV-ALRI (infection-induced immunity) were assumed to develop protective immunity. Administration of nirsevimab could reduce the likelihood of infants experiencing RSV-ALRI associated medical events. We assumed individuals with infection-induced immunity would not experience RSV-ALRI within the follow-up time. The model was constructed using TreeAge Pro 2020 (TreeAge Software, Inc., Williamstown, MA, USA). More model details were provided in the Supplementary material.

Model inputs

There was a total of 124,777 newborns in one year (between 2019 November and 2020 October) in Shanghai according to the latest 2020 population census.[12] We calculated the number of newborns in 12 birth cohorts based on the monthly distribution of 124,777 newborns (Figure S1).[12] The age-stratified RSV-ALRI hospitalization rate among children from 2016 to 2022 in Suzhou city was utilized as a proxy due to its unavailability in Shanghai.[13] This choice was supported by the following considerations: (i) geographic proximity (Shanghai: 31.22° N, 121.46°E; Suzhou: 31.30°N, 120.60°E);[14] (ii) substantial population mobility between the two areas;[15] (iii) comparable levels of economic development (2023 gross domestic product (GDP) per capita: US$ 26866 in Shanghai vs. US$ 26956 in Suzhou) and similar accessibility to healthcare services;[16,17] and (iv) similarities in the seasonality of RSV activity.[18] To account for RSV seasonality, the probability of RSV-ALRI hospitalization was adjusted using the monthly RSV positivity test rate among influenza-like illness cases in sentinel hospitals.[19] The probability of RSV-ALRI outpatient visits was estimated following the methodology described by Liu et al.[10,20] The in-hospital case fatality ratio was derived from a systematic review.[1] The details of calculation were shown in the supplementary material and Figure S2.

Ren et al. examined the costs and quality-adjusted life years (QALY) losses associated with RSV-related hospitalizations among children in Zhengzhou city between 2020 and 2021.[11]

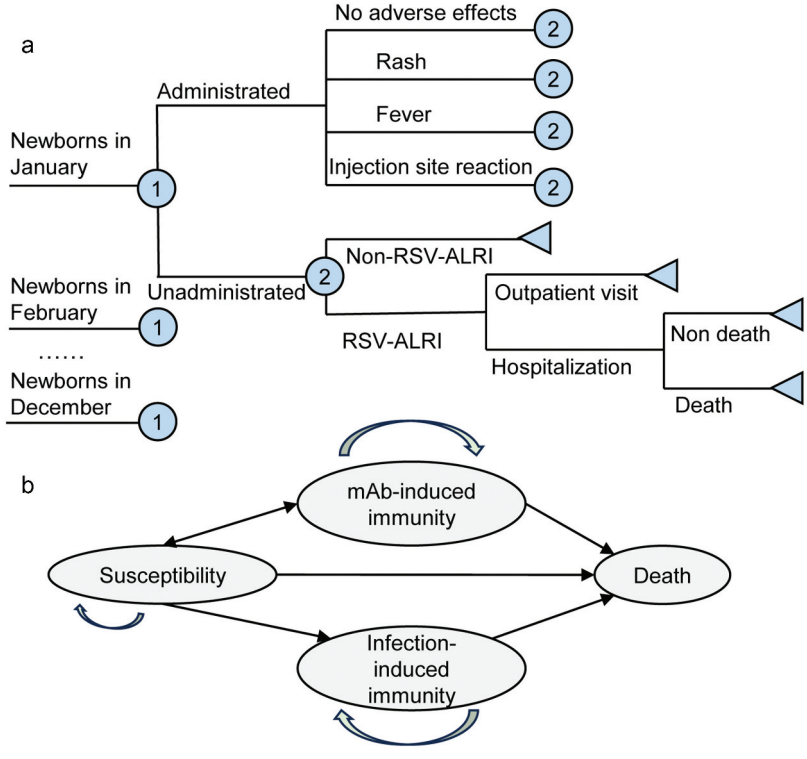

Figure 1. Model framework. Chance nodes labelled with the same number have the same subtree.

In the model, cost of RSV-ALRI outpatient visits was approximated using the cost of influenza-related outpatient services for children.[21] The QALY loss for RSV outpatient cases was derived from a survey conducted in England,[22] which was close to the QALY loss for pediatric influenza outpatient cases in China.[23] The cost of death was assumed to be ten times the cost of a single inpatient stay.[24] The lifetime productivity loss attributable to death was calculated using the human capital approach, assuming a retirement age of 60 years and applying an annual discount rate of 3%.[25] The health utility for infants in the model was assumed to be 1.

Previous cost-effectiveness studies have assumed that the efficacy of nirsevimab could last for five months.[9,26,27] However, emerging evidence indicated that its protection may extend beyond this duration.[7,8,10] Furthermore, phase 3 randomized clinical trial data demonstrated a lower incidence of RSV infections among participants receiving nirsevimab compared to placebo over a 511-day follow-up period.[28] Thus, we modeled two scenarios: (1) a short-duration efficacy scenario, where efficacy persisted for five months and waned entirely by the sixth month,[4] and (2) a long-duration efficacy scenario, where nirsevimab efficacy extended to 24 months based on the estimation by David et al. using a Bayesian framework and clinical trial data.[7] The efficacy declined from 87.6% to 19.0% within the first year and further decreased to 1.3% by the end of the second year (Table S1). Currently, nirsevimab was self-funded and administered voluntarily, similar to the influenza vaccine. A 25% coverage rate for nirsevimab was assumed, using influenza vaccine coverage among children in Shanghai as a proxy.[29,30] Data on adverse events, including rash, fever, and injection site reactions, were sourced from the nirsevimab product information.[31]

The cost of nirsevimab in Shanghai was US$ 263.83 for a 50 mg dose (for infants weighing <5 kg) and US$ 448.48 for a 100 mg dose (for infants weighing ≥5 kg).[32] According to WHO growth standards, the 97th percentile of birth weight was approximately 4.4 kg for boys and 4.2 kg for girls.[33] A large-scale study involving over 24,000 newborns from 13 cities in China further found that all infants weighed less than 5 kg at birth.[34] In the base-case analysis, we assumed all infants received 50 mg dose of nirsevimab. Cost of administration was derived from a national survey.[35] The cost of rash was assumed to be US$ 5, and the cost of fever was assumed to correspond to the cost of self-medication (non-medically attended) due to influenza symptomatic illness.[21] The cost of injection site reaction was derived from one previous study.[24] Side effects of nirsevimab were not assumed to result in health utility losses due to their short duration. All parameters were shown in Table 1.

Cost-effectiveness analysis

Two immunization strategies were evaluated: (1) a year-round approach, in which newborns received a single dose of nirsevimab at birth irrespective of the month, and (2) a seasonal approach, where newborns received a dose of nirsevimab at birth during the RSV epidemic months (October, November, December, January, and February in the base-case analysis).[18,19,36] Costs derived from areas outside Shanghai were adjusted using the ratio of local GDP per capita in 2023.[37] Where appropriate, unit costs were further adjusted to 2023 values using the Consumer Price Index and converted to 2023 US dollars at an exchange rate of 1 US$ = 7.0840 RMB.[38,39] The incremental cost-effectiveness ratio (ICER), defined as the incremental cost per QALY gained, was calculated to compare the cost-effectiveness of the proposed strategies against non-intervention. The formula was followed:

$$ICER = \frac{Cost_{intervention} - Cost_{non-intervention}}{Health\ Utility_{intervention} - Health\ Utility_{non-intervention}}$$

The willingness-to-pay (WTP) threshold was set to US$ 26866, the GDP per capita in Shanghai in 2023.[37]

Sensitivity analysis

Deterministic sensitivity analysis was conducted, and tornado diagrams were generated to assess the impact of parameter ranges on the results. Probabilistic sensitivity analysis (PSA) involving 10,000 Monte Carlo simulations was performed to evaluate the influence of parameter uncertainty on the ICER. Cost-effectiveness acceptability curves were plotted to illustrate the probability of cost-effectiveness for each strategy.

In the base-case analysis, it was assumed that infants were administered nirsevimab from October to February in the seasonal approach (S1). To further investigate the impact of the timing of administration on the outcomes, a sensitivity analysis was conducted (Figure S3). Specifically, approaches S2, S3, and S4 involved initiating nirsevimab administration prior to the onset of the RSV epidemic: S2 began 1 month before the onset, S3 started 2 months prior, and S4 commenced 3 months before the onset.[36] Additionally, the administration period was from October to March, in the S5 approach.

We considered the potential indirect effect of nirsevimab, assuming that unadministrated infants might have a slightly reduced risk of RSV-ALRI-related medical events due to reduced transmission of RSV. As the magnitude of the indirect effect was uncertain,[27] we tested values of 0.5%, 1%, and 5%.[24] The base-case analysis assumed all infants received the 50 mg dose. To account for uncertainty in infant weight at administration, we varied the proportion of infants receiving the 50 mg dose in the sensitivity analysis (80% and 60%), with the remainder receiving the 100 mg dose. Additionally, previous studies have reported a significant association between RSV-ALRI and long-term respiratory outcomes such as recurrent wheezing and asthma in early childhood.[40,41] A scenario analysis was conducted to incorporate the risk of developing recurrent wheezing following an RSV-ALRI hospitalization, based on the modeling framework proposed by Li et al.[42] The probabilities of recurrent wheezing, as well as the associated costs and QALY losses, were obtained from published literature (Table 1).[42–44]

Table 1. Parameters in the model.

Parameters	Baseline value	Range	Distribution
Demographic parameters			
Number of newborns in Shanghai between 2019 November and 2020 October	124,777	–	–
Monthly distribution of newborns	Figure S1	–	–
Epidemiologic parameters			
RSV-ALRI hospitalization rate (per 1000 children-years)	0–5m: 13.9 6–11m: 5.7 12–23m: 2.6	0–5m: 13.1–14.7 6–11m: 5.2–6.2 12–23m: 2.3–2.8	Beta 0–5m: mean: 0.0139; sd: 0.000408 6–11m: mean: 0.0057; sd: 0.000255 12–23m: mean: 0.0026; sd: 0.000128
Probability of an RSV-outpatient case becoming an RSV-inpatient case among children	0.114	0.0775–0.159	Uniform min: 0.0775; max: 0.159
In-hospital case fatality ratio	0–11m: 0.011 12–60m: 0.005	0–11m: 0.008–0.015 12–60m: 0.003–0.010	Beta 0–11m: mean: 0.011; sd: 0.001786 12–60m: mean: 0.0065; sd: 0.001786
Monthly distribution of RSV-ALRI	Figure S2	–	–
Probability of recurrent wheezing following an RSV-ALRI hospitalization	0–11m: 0.31 12–23m: 0.27	0–11m: 0.2567–0.5888 12–23m: 0.2307–0.3101	Beta 0–11m: alpha: 13; beta: 29 12–60m: alpha: 135; beta: 369
Nirsevimab related parameters			
Efficacy of nirsevimab	Table S1	–	–
Cost of nirsevimab	263.83	±20%	–
Cost of administration	7.112	±20%	Gamma mean: 7.112; sd: 0.7257
Proportion of side effects			
Proportion of rash	0.007	–	–
Proportion of fever	0.005	–	–
Proportion of injection site reaction	0.003	–	–
Coverage for nirsevimab	0.25	0.1–0.4	–
Cost of illness and side effects			
Cost of outpatient	0–5m: 122.629 6–23m: 165.694	±20%	Gamma 0–5m: mean: 122.629; sd: 12.5132 6–23m: mean: 165.694; sd: 16.9076
Cost of hospitalization	0–11m: 2349.128 ≥12m: 1870.792	0-11m: 2190.390–2507.892 ≥12m: 1724.910–2016.700	Gamma 0–11m: mean: 2349.128; sd: 80.9954 ≥12m: mean: 1870.792; sd: 74.4362
Cost of recurrent wheezing	0–11m: 340 12–23m: 327	0–11m: 273–409 12–23m: 262–392	Gamma 0–11m: mean: 340; sd: 34.694 12–23m: mean: 327; sd: 33.163
Discounted lifetime productivity	41,001.651	–	–
Annual discount rate	0.03	0.01–0.05	-
Cost of rash	5	±20%	Gamma mean: 5; sd: 0.5102
Cost of fever	10.236	±20%	Gamma mean: 10.236; sd: 1.044
Cost of injection site reaction	170.217	±20%	Gamma mean: 170.217; sd: 17.369
Utilities			
RSV-ALRI outpatient (QALY loss)	0.003823	0.000492–0.012766	Beta mean: 0.006629; sd: 0.003131
RSV-ALRI hospitalization (QALY loss)	0–5m: 0.0097 6–11m: 0.0090 12m–23m: 0.0075	0–5m: 0.0079–0.0114 6–11m: 0.0075–0.0105 12m–23m: 0.0062–0.0089	Beta 0–5m: mean: 0.0097; sd: 0.0008929 6–11m: mean: 0.0090; sd: 0.0007653 12–23m: mean: 0.0075; sd: 0.0006888
Recurrent wheezing (QALY loss)	0–11m: 0.0392 12–23m: 0.0379	0–11m: 0.0116–0.0632 12–23m: 0.0112–0.0614	Beta 0–11m: mean: 0.0392; sd: 0.013163 12–23m: mean: 0.0379; sd: 0.012806

ALRI: acute lower respiratory infections, QALY: quality-adjusted life-years, sd: standard deviation.

Results

Base-case results

Under the year-round approach, a total of 31,195 infants would receive nirsevimab, compared to 14,287 infants under the seasonal approach. Compared to nonintervention, the seasonal and year-round approaches were projected to prevent 3293 (95% uncertainty range [UR]: 2983–3498) and 4999 (95% UR: 4610–5296) RSV-ALRI outpatient cases, respectively, under the short-duration efficacy scenario (Table 2). The QALY losses averted by the seasonal and year-round approaches, relative to nonintervention, were estimated at

Table 2. Results of base case analysis (nirsevimab immunization vs nonintervention) (95% uncertainty range).

Scenario		Number of outpatients averted	Number of inpatients averted	Number of deaths averted	Total cost (US $, million)	Incremental cost (US $, million)	Total QALYs (thousand)	Incremental QALYs (thousand)	ICER
Short-duration efficacy	Seasonal approach	3293 (2983, 3498)	414 (251, 530)	5 (3, 8)	44.01 (43.24, 44.75)	2.21 (1.04, 3.37)	2867.31 (2867.20, 2867.42)	0.16 (0.00, 0.33)	13,073.79 (1477.23, 113261.88)
	Year-round approach	4999 (4610, 5296)	630 (369, 818)	8 (4, 12)	47.75 (47.01, 48.47)	5.95 (4.80, 7.10)	2867.40 (2867.29, 2867.50)	0.24 (0.08, 0.41)	24,323.26 (12,250.89, 82074.89)
	Non- intervention	-	-	-	41.80 (40.92, 42.65)	-	2867.15 (2867.02, 2867.50)	-	-
Long-duration efficacy	Seasonal approach	4197 (3714, 4464)	557 (368, 693)	7 (4, 10)	43.45 (42.70, 44.19)	1.64 (0.48, 2.80)	2867.35 (2867.24, 2867.46)	0.20 (0.03, 0.36)	8111.31 (1178.95, 53027.89)
	Year-round approach	7678 (6829, 8138)	1020 (668, 1272)	12 (7, 18)	46.17 (45.47, 46.85)	4.36 (3.25, 5.52)	2867.50 (2867.40, 2867.60)	0.35 (0.19, 0.51)	12,376.71 (6832.13, 27021.91)
	Non- intervention	-	-	-	41.80 (40.92, 42.66)	-	2867.15 (2867.02, 2867.28)	-	-

QALY: quality-adjusted life-years, ICER: incremental costs per quality-adjusted life year (QALY) gained.

0.16 thousand and 0.24 thousand, respectively. Compared to the seasonal approach, the year-round approach could save an additional 0.08 thousand QALYs at an incremental cost of US$ 3.74 million. The ICER for the seasonal approach and year-round approach was calculated at US$ 13073.79 and US$ 24323.26 per QALY gained respectively, below the WTP threshold.

Compared to the seasonal approach, the year-round approach was estimated to prevent an additional 3482 (95% UR: 3117–3675) outpatient cases, 464 (95% UR: 301–580) hospitalizations, and 6 (95% UR: 4–9) deaths in the scenario of long-duration efficacy. Relative to nonintervention, the seasonal and year-round approaches were projected to save 0.20 thousand and 0.35 thousand QALYs, respectively. The seasonal approach was associated with an incremental cost of US$ 8111.31 per QALY gained, while the ICER for the year-round approach was estimated at US$ 12376.71 per QALY gained.

Results of sensitivity analysis

One-way sensitivity analysis indicated that the results for the seasonal approach versus no intervention were not highly sensitive to parameter variations, and the seasonal approach remained cost-effective across the tested ranges. In the scenario of short-duration efficacy, the year-round approach was highly sensitive to variations in four parameters: the probability of an RSV-outpatient case progressing to an RSV-inpatient case, in-hospital case fatality ratio among children aged ≤12 months, the cost of nirsevimab, and QALY loss for RSV-ALRI outpatients (Figure S4–5). The threshold analysis showed that year-round approach could be cost-effective compared to no intervention when the probability of an RSV-outpatient case becoming an RSV-inpatient case exceeded 0.10943, or case fatality ratio among children aged ≤12 months exceeded 0.0105, or the price of nirsevimab was less than US$ 273.86, or the QALY loss for RSV-ALRI outpatients exceeded 0.00189.

The PSA indicated that the likelihood of seasonal approach being cost-effective was 63.36% at a WTP threshold equivalent to GDP per capita in the scenario of short-duration efficacy (Figure 2). This probability decreased to 27.35% in the scenario of long-duration efficacy. The likelihood of year-round approach being cost-effective was 71.43% under the long-duration efficacy scenario.

The cost-effectiveness outcomes of seasonal approach were influenced by the timing of administration. The S4 strategy (immunization from July to February) averted the highest number of RSV-ALRI medical events compared to other strategies (Table S2). Under the short-duration efficacy scenario, the ICERs for all seasonal strategies (S1 to S5) were below the WTP threshold, with the S1 approach demonstrating the lowest ICER. Under the long-duration efficacy scenario, the S2 approach (immunization from September to February) emerged as the most cost-effective. The probability of the S3 approach being cost-effective under the short-duration efficacy scenario was 24.87%, higher than other seasonal strategies (Figure 3). When long-duration efficacy was assumed, the probability of the S4 approach being cost-effective was 28.66% were higher than that of other strategies.

In the sensitivity analysis incorporating varying levels of indirect protection (0.5%, 1%, and 5%), as the assumed indirect effect increased, both health benefits (including outpatient visits, hospitalizations, and deaths averted) and cost-effectiveness improved (Table S3). When a 5% indirect effect assumed, the ICER of the seasonal approach decreased to US$ 5317.68 per QALY gained in the scenario of short-duration efficacy. The assumed using of nirsevimab doses had a notable impact on the cost-effectiveness results (Table S4). In the scenario of short-duration efficacy, the ICER of seasonal approach increased from US$ 13073.79 to US$ 19526.36 per QALY gained as the share of 100 mg doses rose from 0% to 40%. Notably, when 20% or 40% of infants were assumed to receive the 100 mg dose, the year-round approach would not be cost-effective compared to no intervention in the scenario of short-duration efficacy. Including long-term consequences in the model slightly decreased the ICERs of both immunization strategies (Table S5). For the seasonal approach, the ICER decreased from US$ 8111.31 to US$ 7324.13 per QALY gained under the long-duration efficacy scenario. The year-round approach showed a similar trend but remained less cost-effective than the seasonal approach.

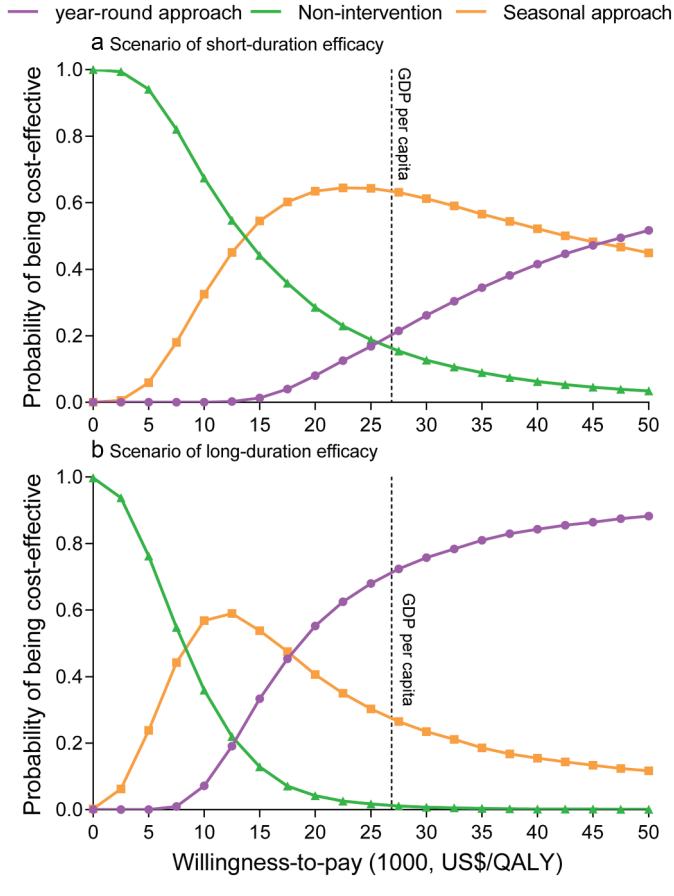

Figure 2. Cost-effectiveness acceptability curves.

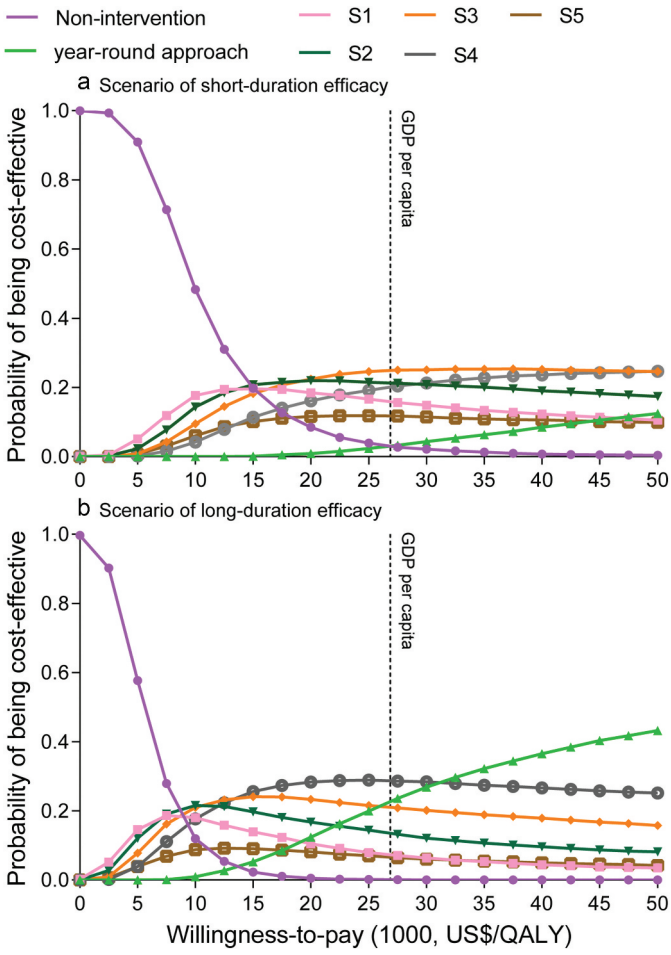

Figure 3. Cost-effectiveness acceptability curves of different seasonal immunization approaches.

Discussion

Our study evaluated the cost-effectiveness of nirsevimab immunization for infants in Shanghai. The nirsevimab immunization could decrease RSV-ALRI associated medical events (i.e., outpatients, hospitalizations, and deaths). At the WTP threshold of GDP per capita, the seasonal and year-round immunization approaches were cost-effective regardless of whether a 5-month or 24-month duration of efficacy was assumed.

Our results and prior studies indicated that using nirsevimab in infants might be cost-effective. Hutton et al. estimated that nirsevimab might have a societal cost of US$ 153,517 per QALY gained based on a decision-tree model in the United States (U.S.).[45] A study in the U.S. conducted by the Centers for Disease Control and Prevention (CDC) found that nirsevimab could save one QALY at a cost of US$ 70430 using static decision-making models.[46] The ICER was sensitive to the cost of nirsevimab. Within the U.S. immunization program, the price of nirsevimab (for both 50 mg and 100 mg) was US$ 395, compared to US$ 520 in the private sector.[47] The price of nirsevimab exceeded that of majority of vaccines. Beyond its impact on cost-effectiveness, the high cost of nirsevimab may pose a barrier to its use. Most of infants' parents might not accept its high price.[48] We suggested that efforts to negotiate lower prices, particularly through bulk purchasing agreements or tiered pricing strategies, might improve accessibility and cost-effectiveness.

The seasonal approach could be more cost-effective than year-round approach, aligning with findings from previous studies.[7,10,26,27] The S1 approach (immunization from October to February) emerged as the optimal approach under the assumption of a five-month duration efficacy. Guo et al. suggested October as the optimal start for seasonal immunization in Shanghai based on a six-month efficacy assumption in the model.[18] During the 2024–2025 RSV season, the first season in which nirsevimab was used, Shanghai municipal CDC recommended initiating nirsevimab immunization in October.[49] However, when efficacy of nirsevimab was assumed to last for 24 months, the optimal immunization strategy shifted to a pre-epidemic approach. Our findings showed that seasonal immunization might ideally commence in September. Notably, the seasonality of RSV activity has been influenced by COVID-19 pandemic.[50] The adjustments to the beginning of seasonal immunization should be informed by additional evidence, including RSV activity surveillance data from the 2024–2025 season. According to the Chinese national sentinel surveillance of acute respiratory infectious diseases, RSV activity demonstrated an increasing trend starting from the 47th week of 2024 (November).[51] Additionally, our findings indicated that administering nirsevimab during the final month of the RSV epidemic was less cost-effective compared to S1 approach, despite its potential to prevent more RSV-ALRI-related medical events.

Our study has several limitations. First, the availability of certain parameters was limited. Epidemiological data, such as the RSV-ALRI hospitalization rate, were sourced from other areas, including Suzhou city, and economic data, such as treatment costs, were adjusted using GDP ratios. Second, our model captured only RSV-ALRI associated medical events. This may have led to an overestimation of the ICER, as some RSV associated clinical outcomes (e.g., RSV-related acute upper respiratory infections) that could potentially be prevented by nirsevimab were not included. Third, while a dynamic transmission model could be more appropriate in modeling the disease transmission process for infectious diseases, its application required detailed transmission and epidemiological data that were currently unavailable for RSV in our study setting. Fourth, maternal antibody-mediated passive immunity was not incorporated into the model, as there is a lack of robust quantitative evidence to reliably parameterize its protection.[52,53] Moreover, available evidence on the association between maternal antibody levels and RSV illness in infants was mixed.[52,53] Maternal RSV vaccination was also not included in the current analysis because it has not yet been approved or implemented in the study setting. Future studies may explore the comparative impact of maternal vaccination once implementation data (e.g. cost and coverage) become available. Lastly, our model assumed that nirsevimab was administered during the birth hospitalization, and therefore did not include economic costs on parents taking their children to receive nirsevimab. However, in real-world settings, the administration may occur after infants' discharge. While this may lead to a slight underestimation of the total cost, our sensitivity analysis suggested that such indirect costs – likely to

be less than 20% of the mAb price (approximately US$ 54)[24]—would not affect the conclusion that nirsevimab remained cost-effective under the modeled scenarios.

Conclusion

Our study, leveraging RSV-associated disease burden and demographic data, offered evidence on the cost-effectiveness of nirsevimab immunization for infants in Shanghai from a societal perspective. A seasonal immunization strategy could be more cost-effective than a year-round approach. Seasonal immunization might optimally initiate approximately one month prior to the onset of the RSV epidemic in Shanghai. More efforts on RSV seasonality surveillance are needed to provide reference for the healthy policy decision regarding the optimal beginning time of seasonal immunization.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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Notes on contributor

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Data sharing statement

The authors confirm that the data supporting the findings of this study are available within the article and its supplementary materials.

Ethical approval

Not applicable. The study did not involve human participants.

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