Poster code: EE57

Assessing Public Health and Economic Benefits of Nirsevimab or RSVpreF for Preventing RSV-Related Outcomes in Japanese Infants

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Current findings suggest that nirsevimab could become a cornerstone of RSV prevention in Japanese national immunization program, offering a comprehensive and effective prophylaxis for all infants

OBJECTIVE

- To evaluate the public health and economic impact of two immunoprophylaxis strategies: universal prophylaxis with nirsevimab and maternal immunisation (MI) with respiratory syncytial virus prefusion F vaccine (RSVpreF), compared to standard of practice (SoP) against respiratory syncytial virus (RSV)-associated lower respiratory tract diseases (LRTDs) in Japanese infants

CONCLUSIONS

Universal immunisation with nirsevimab could substantially reduce both the health burden and the healthcare costs attributable to RSV disease in Japan

Nirsevimab's performance is attributed to its sustained efficacy, timely immunization aligned with Japan's RSV season, and ability to protect all infants regardless of gestational age

BACKGROUND

- RSV infections are a leading cause of LRTDs[1-3]. In Japan, RSV poses a significant health burden on infants[4]. The current SoP provides monthly palivizumab to high-risk infants during RSV season[5]
- Two new options against RSV infections have emerged in Japan, both approved in 2024: Nirsevimab, a monoclonal antibody indicated for all infants through their first RSV season and for high-risk infants in their second season[6], and MI with RSVpreF administered between 28-36 weeks of gestation to protect infants from birth up to 6 months of age[7]
- However, a comprehensive analysis of health and economic outcomes of these preventive options is not yet available in Japan

METHODS

Model structure and perspective: We adapted a static, decision-analytic model tracking Japanese infants through RSV seasons (defined as a duration of 5 months from April to August with a peak in July)[8] to include MI as a prevention strategy, evaluated from a payer perspective

Model input: Comprehensive details of the model have been published previously[4]. Key model input are summarized in **Table 1**

Target population and risk stratification: The model stratified the target population into three groups for RSV-related LRTDs:

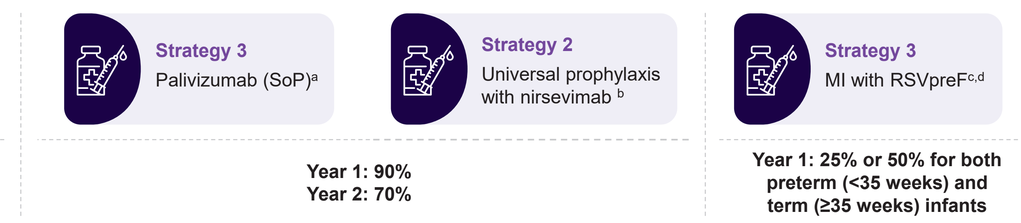
- Late preterm and term infants [≥35 weeks gestational age (wGA)]
- Preterm infants (29 to <35 wGA, ineligible for palivizumab)
- Palivizumab eligible infants: ≤28 wGA and ≤12 months; 29-35 wGA and ≤6 months; or ≤24 months with bronchopulmonary dysplasia, congenital heart disease, immunodeficiency, or down syndrome

Vaccination strategy and uptake: **Figure 1** shows the modelled vaccination strategies and uptake rate

Efficacy assumptions: Protection duration varies across products: palivizumab (30 days)[9], nirsevimab (sustained efficacy for 150 days)[10], and RSVpreF (up to 180 days with waning efficacy over time)[11], after which the model assumes efficacy drops to 0%, following an "on-off" approach

Outcomes: RSV-related hospitalisations, intensive care unit (ICU) admissions, mechanical ventilation, emergency room (ER) visits, outpatient visits, deaths, and recurrent wheezing

Figure 1. Vaccination strategies and Uptake rate



[a]Monthly palivizumab administered during RSV season for eligible infants only, including infants receiving it in their second year. No prophylaxis for preterm and term infants; [b]administered at birth for infants born during RSV season or at season start for those born before; [c]Include two possible implementation strategies for MI: seasonal (targeting pregnancies resulting in births during RSV season, April to August) and year-round, each tested at 25% and 50% uptake (assumption based on real world market uptake research); [d]Complemented by palivizumab for eligible infants with same uptake rates of SoP. Some eligible infants receive palivizumab in their second year

Table 1. Key Model Inputs

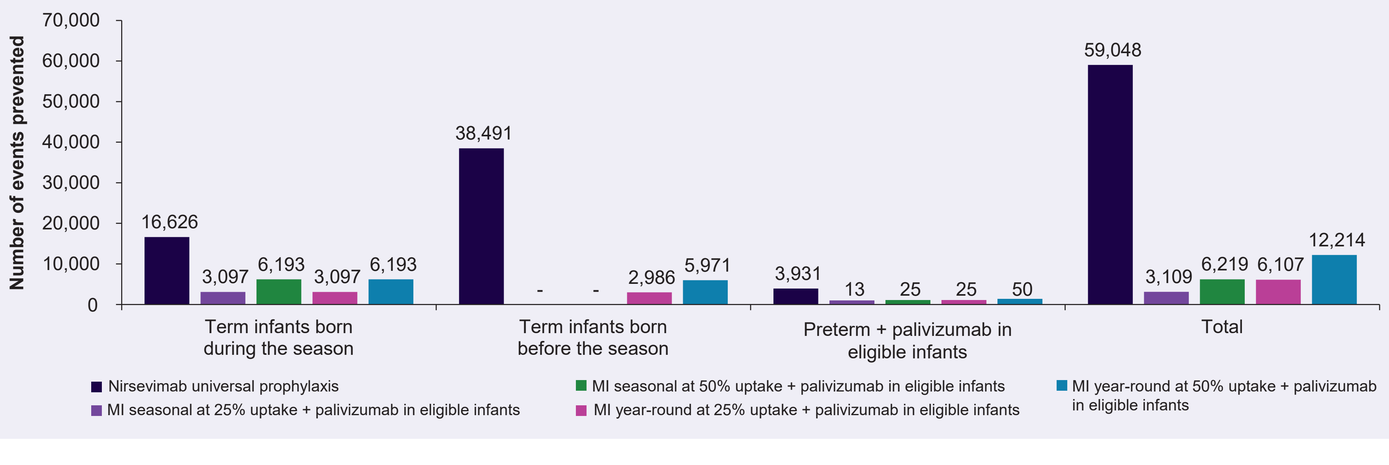
	Palivizumab eligible infants	Preterm infants	Late preterm and term infants
Total annual births[13]		770,747	
Population as % of total annual birth [4,15]	5.5%	1.3%	93.2%
Hospitalization rate (incl. ICU & MV) [15-19]	0 – 11 months : 8.85% 12 – 24 months : 3.04%	0 – 11 months : 2.76%	0 – 11 months : 2.76%
ICU rate[a, 15]	0 – 11 months : 0.05% 12 – 24 months : 0.20%	0 – 11 months : 0.05%	0 – 11 months : 0.05%
Mechanical ventilation (MV) rate[a, 15]	0 – 11 months : 9.05% 12 – 24 months : 2.80%	0 – 11 months : 9.05%	0 – 11 months : 9.05%
ER rate[20]	0 – 11 months : 1.06% 12 – 24 months : 0.36%	0 – 11 months : 0.33%	0 – 11 months : 0.33%
Outpatient rate[15]	0 – 11 months : 8.77% 12 – 24 months : 6.65%	0 – 11 months : 8.77%	0 – 11 months : 8.77%
Probability of wheezing[b, 21]		31.6%	
Mortality associated with RSV hospitalization[19]		0.034%	
Health event costs[19, 20, 22-25]			
Hospitalization		¥391,648	
ICU		¥2,022,198	
MV		¥270,899	
ER		¥10,613	
Outpatient vist		¥2,910	
Wheezing		Year 1: ¥18,333; Year 2: ¥17,966; Year 3: ¥17,607	
Vaccine Efficacy			
RSV-related hospitalizations			
Palivizumab[9]	51%[c]	NA	NA
Nirsevimab[10]	79.5% [95% CI 65·9–87·7])	79.5% [95% CI 65·9–87·7]	79.5% [95% CI 65·9–87·7]
RSVpreF[26]	NA	90 days: 69.7% [95% CI 37.1-86.7][d] 180 days: 55.3% [95% CI 23.8–74.6][d]	
RSV-LRTD			
Palivizumab[9]	51%[c]	NA	NA
Nirsevimab[10]	79.5% [95% CI 65·9–87·7]	79.5% [95% CI 65·9–87·7]	79.5% [95% CI 65·9–87·7]
RSVpreF[26]	NA	90 days: 57.6% [95% CI 31.3-74.6][d] 180 days: 49.2% [95% CI 31.4-62.8][d]	

[a]Conditional on hospitalization; [b]Includes 1st, 2nd, and 3rd year; [c]Efficacy applied prior to the introduction of palivizumab. [d]Adjusted based on weeks gestational age at birth and timing of immunization during pregnancy

RESULTS

- RSV imposes a substantial burden in Japan under SoP, with 116,791 annual RSV-related events including 23,245 hospitalizations, resulting in ¥9.5 billion in total costs
  - Term infants account for 84% of RSV hospitalizations and 89% of all RSV-related events
  - More than half of RSV burden occurs in infants born outside RSV season (59% of all RSV-related events and 55% of hospitalizations)
- Universal prophylaxis with nirsevimab demonstrated a substantial impact by preventing 59,048 events (50.6% reduction), including 12,167 hospitalizations (52.3% reduction), leading to ¥5.0 billion in avoided costs
- MI strategies show variable impact depending on implementation and coverage, preventing between 3,109 and 12,214 events (2.7-10.5% reduction), with 854-3,118 fewer hospitalizations (3.7-13.4% reduction) and ¥0.3-1.3 billion in avoided costs

Figure 2. RSV-related events prevented by subgroups under each strategy



STRENGTH AND LIMITATIONS

- This is the first comprehensive analysis of available RSV prevention strategies for Japanese infants, utilizing high-quality local evidence and recent country-specific data
- An additional strength of this study is the inclusion of MI, which enables a more comprehensive analysis of RSV prevention strategies for Japanese infants
- This analysis utilized a static model that does not account for the transmission of infection or herd immunity. Additionally, we relied on assumptions regarding MI coverage rates based on real-world market uptake research, which may not fully reflect long-term actual implementation

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ABBREVIATIONS: ER, Emergency room; ICU, Intensive care unit; LRTDs, lower respiratory tract diseases; MV, Mechanical ventilation; MI, maternal immunisation; NA, Not applicable; RSV, Respiratory syncytial virus; RSVpreF; Respiratory Syncytial Virus prefusion F vaccine; SoP, standard of practice; wGA, weeks gestational age

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