

Cost-Effectiveness Analysis of Complementary Strategy to protect infants in Romania using Maternal Vaccination with Bivalent Respiratory Syncytial Virus Prefusion F (RSVpreF) Vaccine and Palivizumab



Veronica Purdel¹, Ana Maria Zdrafcovici¹, Oana Falup-Pecurariu², Alexandru Ulmeanu³, Sorin Claudiu Man⁴, Anca C Drăgănescu³, Ali Shajarizadeh⁵, Nishu Gaind⁵, Luka Ivkovic⁵, Gopika Balasubramanian⁵, Rengina Kefalogianni⁶, Diana Mendes⁶
¹Pfizer Romania, Bucharest, Romania; ²Faculty of Medicine, Transylvania University, Romania; ³Department of Pediatrics, Carol Davila University of Medicine and Pharmacy, Romania; ⁴Department 8 – Mother and Child, Iuliu Hațieganu University of Medicine and Pharmacy, Romania; ⁵Evidinno Outcomes Research Inc., Vancouver, BC, Canada; ⁶Pfizer, Tadworth, Surrey, UK;
*Rengina.Kefalogianni@pfizer.com

OBJECTIVE

- Respiratory syncytial virus (RSV) infection is a leading cause of hospitalization for acute respiratory infections in infants.^{1,2}
- In Romania, RSV prevention is limited to palivizumab for high-risk infants only (preterm <35 weeks of gestation [wGA], congenital heart disease, chronic lung disease).³ While high-risk infants face the highest individual risk of severe RSV, the majority of RSV hospitalizations occur among otherwise healthy, full-term infants.^{4,5}
- Recently, the European Medicines Agency approved RSVpreF vaccine for use in pregnant women to prevent RSV illness in infants.⁶
- This study evaluated the cost-effectiveness of introducing RSVpreF maternal vaccination in Romania, with palivizumab used only for high-risk infants not protected by maternal vaccination.

METHODS

- A Markov model was developed to project RSV outcomes in infants and pregnant women and to evaluate the impact of introducing maternal RSVpreF vaccination for all eligible pregnancies, with palivizumab provided to high-risk infants not protected by maternal vaccination, versus palivizumab-only for high-risk infants.
- Unprotected infants are infants whose mother was unvaccinated, or infants born within 2 weeks after maternal vaccination.
- Clinical outcomes included medically-attended RSV cases by care setting (i.e., hospital [H], emergency department [ED], physician's office [PO]), RSV-related deaths in the first year of life (among hospitalized infants), life years (LYs), and quality-adjusted life years (QALYs); economic outcomes included direct medical, indirect, and intervention (RSVpreF vaccine and palivizumab) costs.
- Potential benefits conferred to vaccinated mothers were also considered as part of clinical and economic outcomes.
- Annual number of pregnant women (n = 148,692) and infants (n = 149,384) were from the Romanian National Institute of Statistics.⁷
- RSV incidences were from the BARI study in Spanish children.⁸
- Infant mortality rates were obtained from the Romanian National Institute of Statistics,⁷ while case-fatality rates were derived from a systematic literature review (SLR).⁹
- Vaccine effectiveness was informed by the MATISSE trial efficacy data,¹⁰ assuming 6 months of protection waning linearly to 0% by 9 months of age, and palivizumab effectiveness was based on data from an SLR.¹¹
- An uptake of 16% for the RSVpreF maternal vaccination and an administration window of 26 to 36 wGA were assumed based on expert opinion. Palivizumab uptake was assumed 19.5% among the preterm infants during RSV season (November to March).¹²
- All costs were expressed in 2025 Euros (€). Direct costs of RSV-H [Table 1], RSV-ED (€216.08) and RSV-PO (€130.93) were derived from RSV-related costs in Greece.¹³

Table 1: RSV-related hospitalization cost, by subgroup of interest and age

	<1 month	1-<2 months	2-<6 months	6-<12 months
Full term (≥37 wGA)	€11,999.60	€4,416.42	€2,762.26	€2,029.92
Late preterm (32-36 wGA)	€14,307.34	€11,999.60	€4,416.42	€2,762.26
Early preterm (28-31 wGA)	€19,442.27	€16,784.32	€9,563.06	€6,497.43
Extreme preterm (≤27 wGA)	€33,487.75	€25,094.52	€16,784.32	€12,628.69

- The cost of the maternal vaccine was assumed €166.81, while for palivizumab the cost per dose was €386.20¹⁴ and assumed 5 doses per infant. The administration cost of the vaccine was assumed to be €\$7.88,¹⁵ while the administration cost per dose of palivizumab was assumed to be €13.39.¹⁶
- Workforce participation rates and wage data for the calculation of indirect costs were obtained from the Romanian National Institute of Statistics.^{17,18} Caregiver work loss days and travel costs per episode were sourced from published literature.^{19,20,21}
- General population utility values for the Romanian population were estimated from published data.²² Published RSV-related disutility values for infants (RSV-H= 0.0157, RSV-ED/PO = 0.0061)²³ and caregivers (RSV-H = 0.0066, RSV-ED = 0.0068, RSV-PO = 0.0041)²⁴ were applied.
- To estimate the potential benefits of RSVpreF vaccination among pregnant women, the following inputs were captured [Table 2]:

Table 2: Inputs related to RSV burden and prevention in pregnant women

Model Parameter	Value		
Average age of pregnant women ⁷	29 years		
	Hospital	ED	PO
Annual rate of RSV/100,000 – Years 1-5 ^{25,26}	26.89	310.60	2,074.25
Annual rate of RSV/100,000 – Years 6+ ^{25,26}	151.29	436.16	3,203.87
QALY loss per RSV episode ^{27,28}	0.0167	0.0054	0.0054
Medical care cost per episode – Years 1-5 ²⁹	€1,913.91	€263.69	€178.54
Medical care cost per episode – Years 6+ ²⁹	€3,097.28	€310.59	€225.43
Indirect cost per episode ^{18,30}	€590.89	€78.79	€78.79
RSVpreF effectiveness ^{31,32}	Derived from RENOIR clinical trial		

ANALYSIS

- The base analysis assumed an annual discount rate of 3% applied to both future costs and outcomes, and a time horizon of lifetime.
- Scenario analysis tested the impact of improved vaccine uptake (54% as achieved in the United Kingdom maternal program).³³

RESULTS

- Maternal RSVpreF vaccination, with palivizumab only to high-risk infants not protected by maternal vaccination, was projected to prevent 2,835 RSV cases (743 RSV-H, 776 RSV-ED, and 1,316 RSV-PO) compared with palivizumab alone in high-risk infants.
- Maternal RSVpreF vaccination with palivizumab would result in cost savings of €1.03 million (M; incl. healthcare savings €0.64M) coupled with a gain of 48 QALYs compared to palivizumab alone.
- From healthcare and societal perspectives, maternal vaccination with RSVpreF with complementary use of palivizumab among unprotected high-risk infants would be a dominant strategy *versus* palivizumab alone. [Table 3].

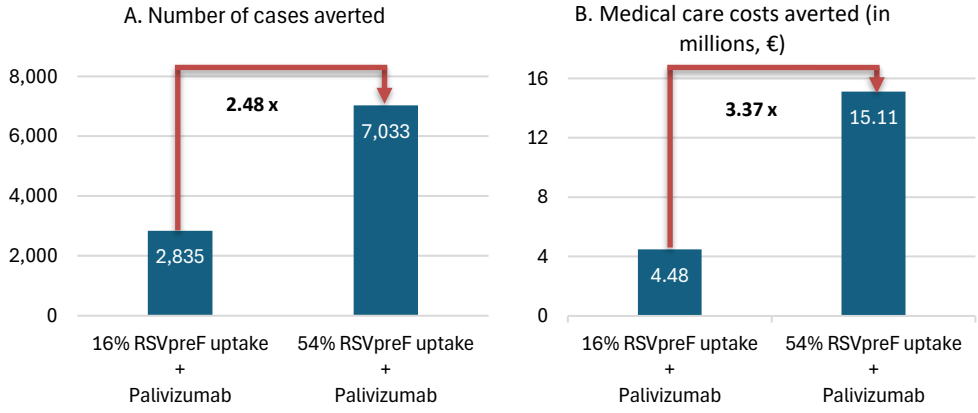
Table 3: Base case analysis results

	Palivizumab for high-risk infants	Maternal RSVpreF + Palivizumab for unprotected infants	Difference
Clinical outcomes among infants			
No. of cases – RSV H	9,293	8,562	-731
No. of cases – RSV ED	13,627	12,989	-638
No. of cases – RSV PO	18,871	18,156	-715
No. of RSV-related deaths	7	6	-1
Life years (discounted)	4,510,434	4,510,449	14
QALYs (discounted)	4,040,747	4,040,779	32
Caregivers' QALYs lost (discounted)	226	214	-12
Clinical outcomes among mothers			
No. of cases – RSV H	1414	1402	-12
No. of cases – RSV ED	5043	4905	-137
No. of cases – RSV PO	36809	36208	-601
Life years (discounted)	592,489	592,489	0
QALYs (discounted)	488,427	488,431	4
Economic outcomes (in millions €)			
Medical care among infants	50.79	46.47	-4.32
Medical care among mothers	6.67	6.51	-0.16
Maternal vaccination costs	0	3.96	3.96
Palivizumab costs	4.68	4.56	-0.12
Total direct costs	62.14	61.50	-0.64
Total indirect costs	8.80	8.41	-0.39
Total costs (direct + indirect)	70.94	69.91	-1.03
ICER, cost per QALY gained (€)			
Healthcare perspective	Dominant		
Societal perspective	Dominant		

Dominant, i.e. more effective and less costly (cost saving)

- Increasing overall vaccine uptake from base case to 54%, would prevent 2 and 3 times as many RSV-related cases and medical care costs, respectively (Figure 1), highlighting the importance of coverage for the success of the vaccination program in averting RSV-related burden among infants and pregnant women in Romania.

Figure 1: Total number of RSV cases averted (A) and RSV medical care costs averted (B) (RSVpreF + Palivizumab [unprotected infants] vs. Palivizumab [high-risk infants]) for base case vaccine uptake and scenario 54% vaccine uptake



CONCLUSION

- A complementary prophylaxis of maternal RSVpreF vaccine and palivizumab used only for high-risk infants not protected by maternal vaccination is likely a cost-saving strategy.
- A high number of hospitalizations, ED and PO visits could be prevented with RSVpreF vaccine, and palivizumab used only for high-risk infants not protected by maternal vaccination, along with reducing economic burden associated with RSV, among pregnant women and infants in Romania.

REFERENCES

1. CDC. About RSV. 2. Ciapponi et al. Front Public Health. 2024. 3. Calomfirescu-Avramescu et al. Vaccines. 2025. 4. Wildenbeest et al. Lancet Respir Med. 2023. 5. Halasa et al. JAMA Netw Open. 2023. 6. EMA. Abrysvo. 7. National Institute of Statistics. Vital Statistics. 8. Martínón-Torres et al. BMC Infect Dis. 2022. 9. Li et al. Lancet. 2022. 10. Simões et al. Obstet Gynecol. 2025. 11. Garengani et al. Cochrane Database Syst Rev. 2021. 12. IQVIA. MIDAS database. 13. Gourzoulidis et al. Front Public Health. 2025. 14. National Catalogue of Prices for Authorized Medicines. 2025. 15. Ministry of Health. Technical norms for the implementation of national public health programs. 16. National Insurance House. 2025. 17. National Institute of Statistics. Labour Force in Romania Employment and Unemployment. 18. National Institute of Statistics. The average gross salary in the economy in July 2025. 19. Miron et al. Viruses. 2023. 20. Sankatsing et al. Influenza Other Respir Viruses. 2025. 21. Zhang et al. J Infect Dis. 2020. 22. Olariu et al. Health Qual Life Outcomes. 2023. 23. Roy., Deriving health utility weights for infants with Respiratory Syncytial Virus (RSV). 24. Hutton et al. Economic Analysis of Nirsevimab in Pediatric Populations. 25. Burkart et al. EClinicalMedicine. 2025. 26. Li et al. Open forum infectious diseases. 2025. 27. Falsey et al. Influenza Other Respir Viruses. 2022. 28. Mao et al. J Infect Dis. 2022. 29. Gourzoulidis et al. Vaccines. 2024. 30. Averin et al. Expert Rev Vaccines. 2025. 31. Walsh et al. N Engl J Med. 2023. 32. Davis et al. Clin Infect Dis. 2024. 33. UK Health Security Agency. Respiratory syncytial virus (RSV) maternal vaccination coverage in England: May 2025.

Declaration of financial/other relationships: AS, NG, LI, and GB are employees of Evidinno Outcomes Research, which received funding from Pfizer for this study and preparation of this poster. VP, AMZ, RK, and DM are employees of Pfizer and may hold stock or stock options.