Cost-Effectiveness of Mixed-Approach Maternal RSVpreF/Infant Nirsevimab Immunization versus Nirsevimab Alone for Prevention of Respiratory Syncytial Virus in Spain

EE261

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INTRODUCTION

- Respiratory syncytial virus (RSV) is a major driver of demand for medical care among children in Spain, with the most severe outcomes occurring in RSV cases that manifest as lower respiratory tract illness (LRTI; RSV-LRTI)[1]
- The burden of RSV-LRTI is particularly high in children aged <1 year, those with risk factors, and those born premature[1]
- The Spanish Ministry of Health (MoH) recommended administration of monoclonal antibody nirsevimab in all infants aged <6 months and high-risk infants aged <24 months, beginning in 2023[2]
- Maternal vaccination via bivalent stabilized prefusion F subunit vaccine (RSVpreF) is also licensed in Europe to protect infants against RSV, though not currently recommended by the Spanish MoH[3]

OBJECTIVE

To evaluate the cost-effectiveness of an immunization program with RSVpreF for pregnant women plus nirsevimab for infants not yet protected (herein, "Mixed Approach") compared to standard of care nirsevimab use (herein, "Nirsevimab Alone") to prevent RSV-LRTI among infants in Spain

METHODS

Model Overview

- Population-based cohort model was employed to depict clinical and economic outcomes associated with RSV-LRTI among infants aged <1 year and the impact of prevention strategies comprising RSVpreF and/or nirsevimab:
  - Clinical outcomes included cases of medically attended RSV-LRTI characterized by care setting (hospital [RSV-H], emergency department [RSV-ED], primary care [RSV-PC]) and attributable deaths
  - Economic costs included direct costs related to medical care and intervention use, as well as indirect costs related to caregiver work loss and lost future earnings due to premature RSV-LRTI-related death
- Model population was characterized by month of age, calendar month of birth, and term status defined by gestational age in weeks (wGA) at birth (full-term [FT], ≥37 wGA; late preterm [LP], 32-36 wGA; early preterm [EP], 28-31 wGA; extreme preterm [ExP], ≤27 wGA)
- Model inputs are reported in Table 1 with details included in Supplementary material

Table 1. Model Inputs

Parameter	Value	Reference
Infant population	360,633	4
Distribution of live births	FT: 92.9%; LP: 6.1%; EP: 0.8%; ExP: 0.3%	4
Incidence rates	*See Table 2*	1, 5-7
Case-fatality rate	0.17 per 100 hospitalizations	1
General population mortality	*See Supplementary Material*	4, 8
Intervention uptake	RSVpreF: 71.4%; nirsevimab (in-season): 91.0%; nirsevimab (catch-up): 76.5%	9-10
Intervention effectiveness	*See Figure 1*	11-13
Intervention costs*	RSVpreF: 166.50 €; nirsevimab: 699.91 €	14-15
Administration costs	RSVpreF: 6 €; nirsevimab (in-season): 0 €; nirsevimab (catch-up): 6 €	16
Hospitalization costs	*See Table 3*	17
RSV-ED costs	<1 month: 418 €; 1-<2 months: 472 €; 2-<6 months: 515 €; 6-<12 months: 561 €	1
RSV-PC costs	<1 month: 466 €; 1-<2 months: 565 €; 2-<6 months: 601 €; 6-<12 months: 581 €	1
Cost of caregiver work loss	RSV-H: 222 €; RSV-ED: 214 €; RSV-PC: 165 €	18-20, 1
Cost of RSV-related mortality	252,440 €	19, 21
Infant QALY loss	RSV-H: 0.0157; RSV-ED/PC: 0.0061	22

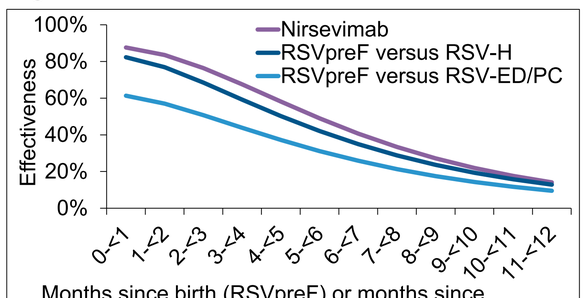
*Reflective of public prices discounted at a rate of 7.5%, in accordance with Royal Decree-Law

Table 2. Incidence Rates

	Month of Age				
	<1	1-<2	2-<3	3-<6	6-<12
RSV-H (**Scenario 1**)*					
FT	36	36	36	34	9
LP	62	62	62	83	15
EP/ExP	17	17	17	80	61
RSV-H (**Scenario 2**)*					
FT	93	89	48	25	9
LP	162	155	84	63	15
EP/ExP	44	42	23	60	60
RSV-ED					
FT	86	89	49	25	9
LP	150	155	86	63	15
EP/ExP	41	42	23	60	61
RSV-GP					
FT	86	85	48	25	9
LP	150	148	84	61	15
EP/ExP	41	40	23	58	58

*Alternative hospitalization rates were employed due to high variation in estimated incidence across sources[1,5]

Figure 1. Effectiveness of Interventions*



*RSVpreF effectiveness assumed to be 0% for infants born <2 weeks after administration or born EP/ExP

Table 3. Hospitalization Costs

	Month of Age			
	<1	1-<2	2-<6	6-<12
FT	4,519 €	3,749 €	3,460 €	3,506 €
LP	7,913 €	7,291 €	7,159 €	3,506 €
EP	10,275 €	9,305 €	6,216 €	3,506 €
ExP	47,028 €	30,095 €	10,051 €	3,506 €

Analyses

- Base case analyses employed two alternative RSV-H rates (Table 2; Scenario 1, Scenario 2) to evaluate the cost-effectiveness of Mixed Approach versus Nirsevimab Alone
- RSVpreF was administered seasonally (targeting infants born October-March) to pregnant women between 24-36 weeks gestation
- Infants were considered protected by RSVpreF only if (1) their mother received the vaccine during pregnancy, (2) they were born >2 weeks after administration, and (3) they were born at >31 wGA; among infants not protected via RSVpreF, infants may receive nirsevimab according to the following schedule:
  - Infants born during RSV season (October-March) receive nirsevimab at birth
  - Infants born April-September (catch-up) receive nirsevimab in October
- Scenario analyses were conducted in which effectiveness inputs were truncated based on duration of clinical trial follow-up (RSVpreF: 6 months; nirsevimab: 5 months)
- Probabilistic sensitivity analyses (PSA) were also conducted to account for uncertainty surrounding estimates of key model parameters
- Costs are reported in 2024 Euros; future costs and QALYs were discounted 3% annually[23]

RESULTS

BASE CASE ANALYSES

- In both Scenario 1 and Scenario 2, the Mixed Approach (vs. Nirsevimab Alone) yielded fewer hospitalizations (Table 4), with the greatest impact observed amongst infants aged <1 month (Figure 2)
- With lower intervention costs and reduced burden of severe disease, Mixed Approach reduced total costs by 25% in both Scenario 1 and Scenario 2 (Figure 3)
- Mixed Approach was found to be dominant over Nirsevimab Alone in both scenarios

Table 4. Clinical outcomes with Mixed Approach vs. Nirsevimab Alone among infants in Spain

	Scenario 1			Scenario 2		
	Mixed Approach	Nirsevimab Alone	Difference	Mixed Approach	Nirsevimab Alone	Difference
Use of interventions						
No. women receiving RSVpreF	127,513	---	127,513	127,513	---	127,513
No. infants receiving nirsevimab	186,323	301,644	-115,322	186,323	301,645	-115,322
Clinical outcomes						
No. of cases						
RSV-H	3,467	3,600	-134	4,137	4,553	-416
RSV-ED	6,040	5,484	556	6,040	5,484	556
RSV-GP	5,860	5,326	534	5,860	5,326	534
No. of RSV-related deaths	6	6	0	7	8	-1
Life years	10,962,721	10,962,715	6	10,962,726	10,962,706	20
QALYs*	10,530,633	10,530,631	2	10,530,627	10,530,608	19

*Includes infant QALYs minus QALYs lost among caregivers

Figure 2. RSV-related hospitalizations by month of age

Figure 2A. Scenario 1

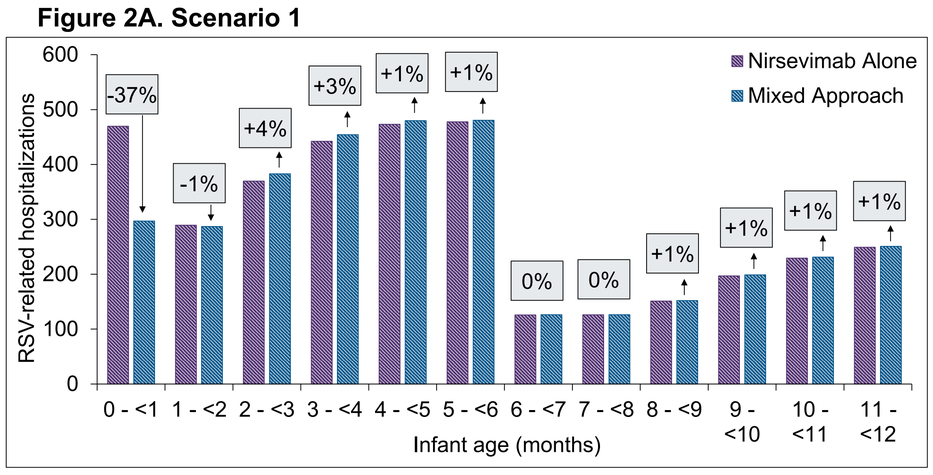


Figure 2B. Scenario 2

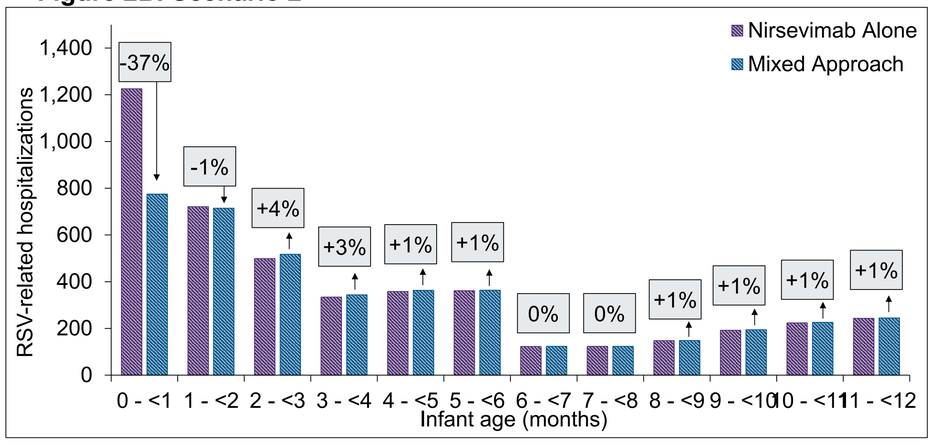


Figure 3. Costs by type

Figure 3A. Scenario 1

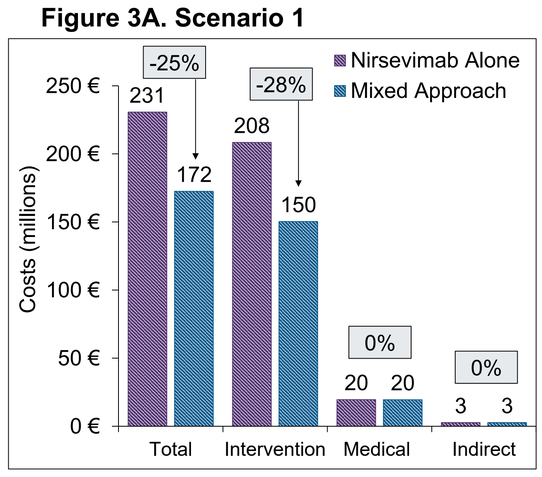
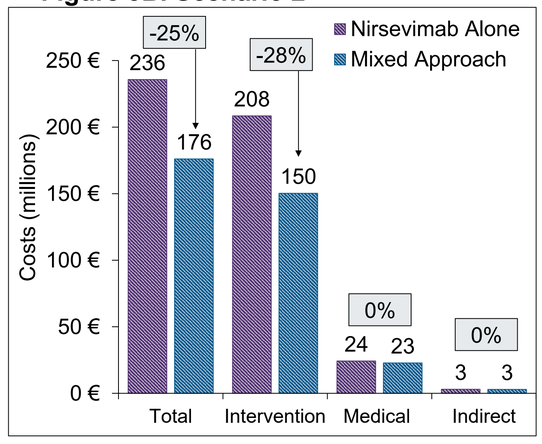


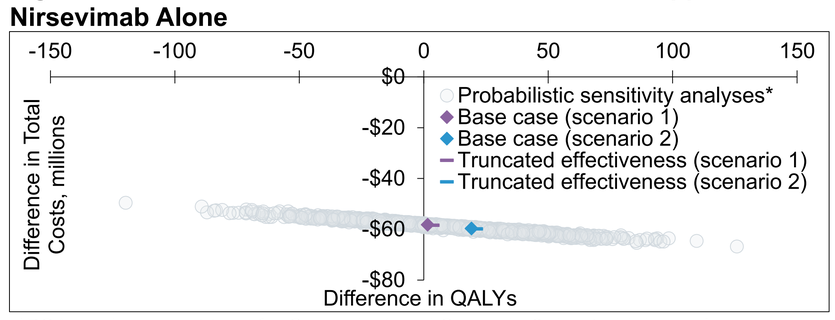
Figure 3B. Scenario 2



SENSITIVITY AND SCENARIO ANALYSES

- Applying truncated intervention effectiveness had a minor impact on results (Figure 4)
- In PSA, 48% (Scenario 1) and 71% (Scenario 2) of simulations yielded dominance of Mixed Approach; in all remaining simulations, Mixed Approach yielded lower costs than Nirsevimab Alone but also lower QALYs, demonstrating the similar clinical impact across strategies

Figure 4. Difference in Costs and QALYs with Mixed Approach vs. Nirsevimab Alone



*PSA markers combined for Scenario 1 and Scenario 2 due to high overlap

LIMITATIONS

- Data source for effectiveness[11] employed endpoints from clinical trial data which may not perfectly align with model outcomes; data limitations also required that nirsevimab effectiveness be assumed invariant by infant age at administration and disease severity
- Data specific to Spain were employed for most inputs; however, some model parameters (e.g., relative risk of incidence by term status, QALY loss) required the use of data from comparable country settings
- Several outcomes were not captured by the model, including benefits of RSVpreF for pregnant women, indirect impact of interventions on other populations, and the potential prevention of non-medically attended disease, upper respiratory tract infections, or long-term consequences of illness

CONCLUSIONS

- **In Spain, vaccinating pregnant women with RSVpreF and administering nirsevimab to infants not yet protected would be more effective against severe disease and would substantially reduce the economic burden of RSV-LRTI, compared to use of nirsevimab alone**
- **Findings demonstrate that employing RSVpreF use via a complementary approach would thus be a more cost-effective use of resources compared to the strategy currently employed**

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