Nirsevimab effectiveness against hospitalized Respiratory Syncytial Virus infection in Portugal, 2024/25 season

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Background

- ✓ **RSV** = leading cause of lower respiratory tract infections in young children.
- ✓ In **mainland Portugal**, a **Nirsevimab immunisation programme** started in **October 2024**, targeting:
  - ✓ All children **<3 months**, and
  - ✓ **High-risk** children **<24 months**.
- ✓ **Objective:** to estimate **Nirsevimab effectiveness (NE)** against RSV-associated hospitalisations in Portugal during the 2024/2025 season.

Methods

- ✓ **Study Design:** Test-negative case-control, 15 hospitals VigiRSV (Portuguese Network for RSV Surveillance).

- ✓ **Population:** Children <24 months eligible for immunisation, hospitalised with **severe acute respiratory infection (SARI).**

  Cases: RSV-positive (RT-PCR or RAT); **Controls:** RSV-negative (RT-PCR or RAT)

- ✓ **Analysis:** Logistic regression adjusted for: age group, sex, onset month, low birth weight, prematurity, chronic condition. **Nirsevimab effectiveness (NE):** (1 – adjusted OR of immunisation) × 100

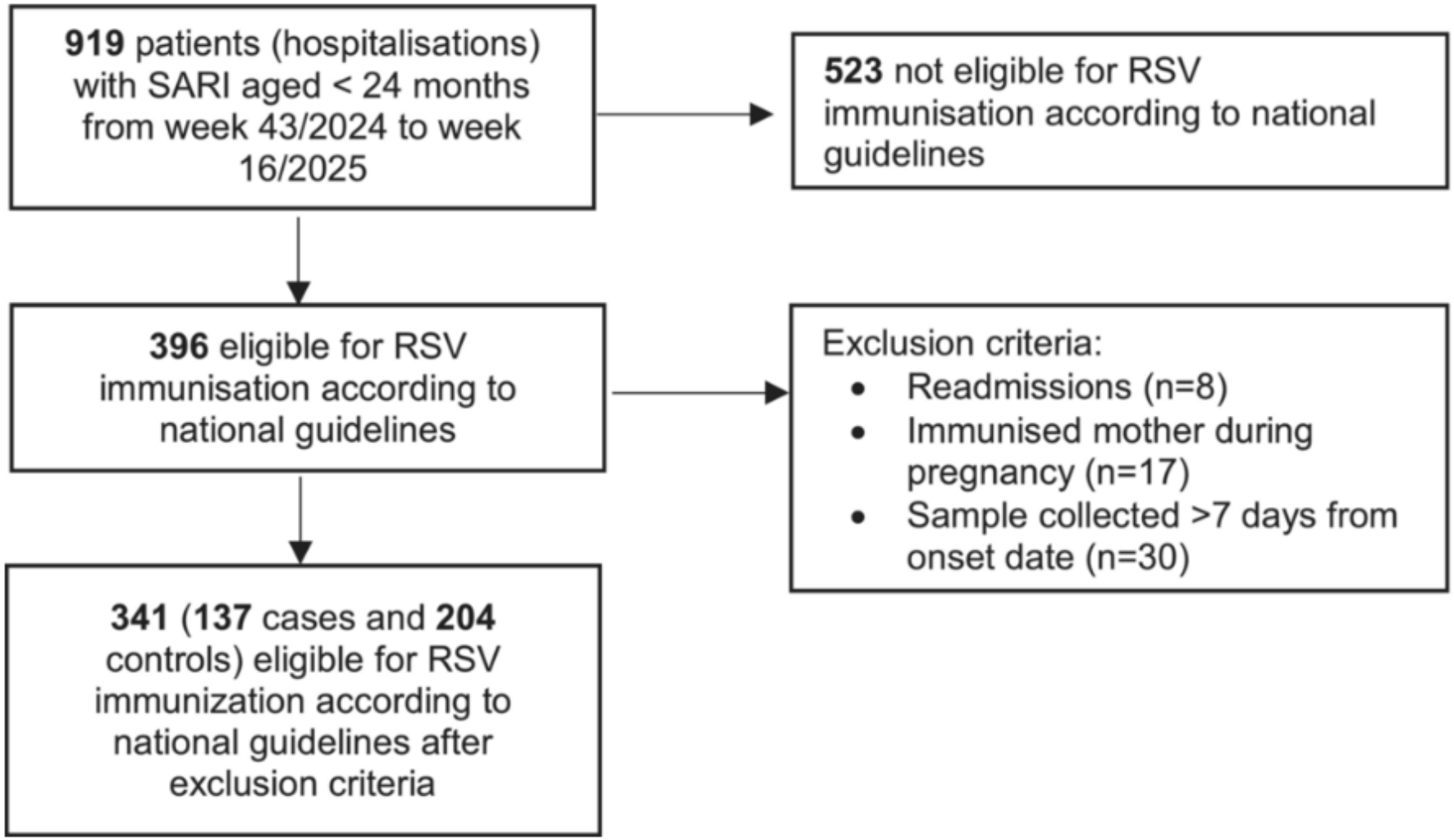
  Sensitivity analysis:

  (1) Only PCR tested

  (2) Immunisation at least 7 days before onset date instead of 2 days

  (3) Without Madeira data

Figure 1. Flow chart of participants selected for the study



Results 2

Figure 2. Distribution of cases and controls on the epidemic curve, considering the study period between week 43/2024 and week 16/2025.

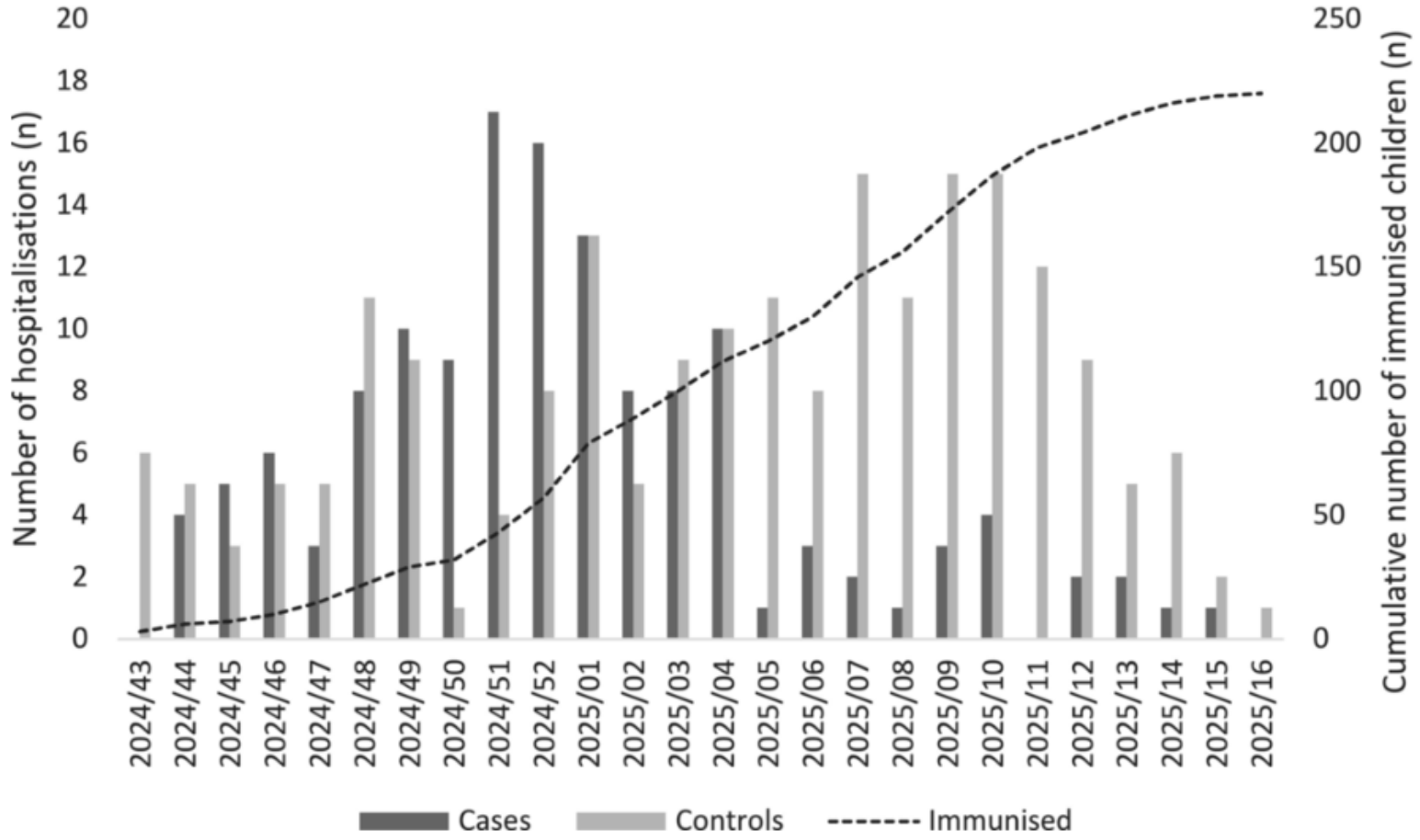


Table 1. Cases and controls characterization.

Characteristics	Total (n=341)	Cases (n=137)	Controls (n=204)	p-value (Cases vs Controls)
Age group n=341				0.01
<1 month	60 (17.6%)	15 (11.0%)	45 (22.1%)	
1-2 months	143 (41.9%)	65 (47.4%)	78 (38.2%)	
3-5 months	76 (22.3%)	33 (24.1%)	43 (21.1%)	
6-11 months	41 (12.0%)	20 (14.6%)	21 (10.3%)	
12-23 months	21 (6.2%)	4 (2.9%)	17 (8.3%)	
Age (median, IQR) –months n=341	2 (1-4)	2 (1-3)	2 (1-4)	0.28
Sex (% males) n=341	224 (65.7%)	88 (64.2%)	136 (66.7%)	0.73
Prematurity* (%) n=322	73 (22.7%)	28 (21.4%)	45 (23.6%)	0.92
Low birth weight** (%) n=310	68 (21.9%)	27 (21.3%)	41 (22.4%)	0.75
Chronic condition*** (%) n=341	30 (8.8%)	11 (8.0%)	19 (9.3%)	0.83
Nirsevimab immunisation (%) n=341	220 (64.5%)	61 (44.5%)	159 (77.9%)	<0.01
Days between immunisation and symptoms onset (median in days, IQR) n=341	48.0 (25.8-76.3)	49.0 (34.0-59.0)	47.0 (17.0-79.0)	0.73

* Prematurity was defined as gestational age <37 weeks. ** Low birth weight was defined as birth weight <2500 grams. *** Chronic conditions included the following: congenital heart disease, velocardiofacial syndrome, chronic lung disease, trisomy 21, immunodeficiency, and neuromuscular disease. Differences in categorical variables were assessed using Pearson's Chi-squared test. Continuous variables were compared using the Wilcoxon rank-sum test.

Results 4

Table 2. Nirsevimab effectiveness against RSV-related hospitalisations among children under 24 months during the 2924/2025 RSV season, in Portugal.

	Cases, NI (n/n, %)	Controls,NI (n/n, %)	NE (%) crude (95% CI)	NE (%) adjusted (95% CI)*
Primary analysis (n=341)	61/137, 44.5%	159/204, 77.9%	77.3 (63.8-86.0)	**78.5 (59.3-89.0)**
Sensitivity analysis				
Only RT-PCR-tested (n=255)	46/101, 45.5%	126/154, 81.8%	81.4 (67.5-89.6)	82.0 (62.0-91.8)
Immunisation at least 7 days before the onset date instead of 2 days (n=341)	63/137, 46.6%	161/204, 78.9%	77.3 (63.6-86.0)	76.2 (55.2-87.7)
Without Madeira data (n=329)	60/134, 44.8%	153/195, 78.5%	77.7 (64.2-86.4)	79.1 (59.5-89.6)

*adjusted by age group (<1, 1-2, 3-5, 6-11, 12-23 months), sex (male/female), month of infection (oct24/nov24/dez24/jan25/fev25/mar25/apr25), chronic condition (Yes/No), prematurity (Yes/No), low birthweight (Yes/No). NE: Nirsevimab Effectiveness; NI: Nirsevimab immunisation

Discussion/Conclusions 1

Nirsevimab Effectiveness (Portugal, 2024/2025)

- 78.5% (95% CI: 59.3–89.0%) against RSV-related hospitalisation
- Consistent with other countries (73–98%) → confirms high protection

Sensitivity analyses

- Consistent findings using only RT-PCR–confirmed cases
- Low risk of misclassification bias

Coverage

- 77.9% coverage among controls, lower than other NIP vaccines
- Useful to explore factors linked to non-immunisation in the next campaigns

Discussion/Conclusions 2

✓ **Limitations**

Observational test-negative design → residual confounding

Sample: 341 children / 15 hospitals may not represent all cases

Limited national coverage data → possible selection bias

First national season of Nirsevimab implementation→ generalizability limited

✓ **Ongoing surveillance:** continued monitoring is essential to track potential viral evolution after universal immunisation.

Thank you!

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