#2630

BOLOGNA
& ONLINE
1-5 JUNE
2026

RSV hospitalisation burden in high-risk infants across two seasons of universal prophylaxis with nirsevimab: The NIRSE-GAL study

Presented By: Federico Martinón-Torres

44TH ANNUAL MEETING OF THE
EUROPEAN SOCIETY FOR
PAEDIATRIC INFECTIOUS DISEASES
Organised jointly by ESPID and the ESPID Foundation

#ESPID2026
espidmeeting.org

#2630

RSV hospitalisation burden in high-risk infants across two seasons of universal prophylaxis with nirsevimab: The NIRSE-GAL study

Josefina L. Razzini M.D.[1,2,3,4#], Iago Giné-Vázquez Ph.D.[1,2,3#], Jing Jin Ph.D.[5#], María-Isolina Santiago-Pérez BS[6], Olaia Pérez-Martínez M.D.[6], María-Teresa Otero-Barrós M.D.[6], Nuria Suárez-Gaiche M.D.[6], Rolf Kramer Ph.D.[5], Leticia Platero-Alonso MSc.[7], Rosa-María Álvarez-Gil M.D.[8], Olga-María Ces-Ozores RPH[8], Victoria Nartallo-Penas Ph.D.[8], Susana Mirás-Carballal RPH[8], Marta Piñeiro-Sotelo RPH[6], Juan-Manuel González-Pérez BS[9], Carmen Rodríguez-Tenreiro-Sánchez Ph.D.[1,2,3], Ángela Manzanares-Casteleiro M.D.[1,2,3,10], Andrés Muy-Perez, M.D[1,2,3,10], Ana Isabel Dacosta-Urbieta M.D.[1,2,3,10], Cintia Álvarez-Smith M.D.[1,2,3,10], Irene Rivero-Calle M.D.[1,2,3,10], Prof. Antonio Salas Ph.D.[3,11,12], Carmen Durán-Parrondo Ph.D.[13], Narmeen Mallah Ph.D.[1,2,14,16], #Prof. Federico Martinón-Torres Ph.D. (https://orcid.org/0000-0002-9023-581X) [1,2,3,10#].

[1] Genetics, Vaccines and Pediatric Infectious Diseases Research Group, Instituto de Investigación Sanitaria de Santiago de Compostela (IDIS), Santiago de Compostela, Galicia, Spain; [2] WHO Collaborating Centre for Vaccine Safety, Santiago de Compostela, Galicia, Spain; [3] Centro de Investigación Biomédica en Red de Enfermedades Respiratorias (CIBERES), Instituto de Salud Carlos III, Madrid, Spain; [4] International School for PhD Studies of the University of Santiago (EDIUS), University of Santiago de Compostela (USC), Galicia, Spain. [5] Sanofi Vaccines, Lyon, France; [6] Department of Epidemiology, Dirección Xeral de Saúde Pública, Consellería de Sanidade, Xunta de Galicia, Galicia, Spain; [7] Sanofi Vaccines, Madrid, Spain; [8] Department of Communicable Diseases, Dirección Xeral de Saúde Pública, Consellería de Sanidade, Xunta de Galicia, Galicia, Spain; [9] Subdirección de Sistemas y Tecnologías de la Información, Consellería de Sanidade, Xunta de Galicia, Galicia, Spain; [10] Translational Pediatrics and Infectious Diseases, Hospital Clínico Universitario de Santiago (SERGAS) and University of Santiago de Compostela (USC), Santiago de Compostela, Galicia, Spain; [11] Genética de Poblaciones en Biomedicina (GenPoB) Research Group, Instituto de Investigación Sanitaria de Santiago de Compostela (IDIS), Hospital Clínico Universitario de Santiago (SERGAS), Galicia, Spain; [12] Unidade de Xenética, Instituto de Ciencias Forenses, Facultade de Medicina, Universidade de Santiago de Compostela (USC), Galicia, Spain; [13] Dirección Xeral de Saúde Pública, Consellería de Sanidade, Xunta de Galicia, Galicia, Spain; [14] Department of Preventive Medicine, University of Santiago de Compostela (USC), Santiago de Compostela, Galicia, Spain; [15] Institute of Psychology (IPSIUS), University of Santiago de Compostela, Spain; [16] Centro de Investigación Biomédica en Red de Epidemiología y Salud Pública (CIBER-ESP), Instituto de Salud Carlos III, Madrid, Spain.

[#]JLR, IG-V, JJ, NM and FM-T contributed equally to this work.

**Corresponding author: federico.martinon.torres@sergas.es / https://orcid.org/0000-0002-9023-581X*

Conflict of Interest

Company / Name	Honoraria / Expense*	Consulting / Advisory Board	Funded Research	Royalties / Patent	Stock Options	Ownership / Equity Position	Employee
Astra-Zeneca	FMT	-	-	-	-	-	-
GlaxoSmithKline	FMT	FMT	-	-	-	-	-
Janssen	FMT	FMT	-	-	-	-	-
Medimmune	FMT	FMT	-	-	-	-	-
Moderna	FMT	FMT	-	-	-	-	-
MSD	FMT	FMT	-	-	-	-	-
Novavax	FMT	-	-	-	-	-	-
Novartis	FMT	-	-	-	-	-	-
Pfizer	FMT	FMT	-	-	-	-	-
Regeneron	FMT	-	-	-	-	-	-
Roche	FMT	-	-	-	-	-	-
Sanofi	FMT	FMT	-	-	JJ, RK, LPA	-	JJ, RK, LPA
Seqirus	FMT	FMT	-	-	-	-	-

*Honoraria paid to institution – principal investigator
FMT, F. Martinón-Torres**; JJ,** J. Jin**; LPA,** L. Platero-Alonso**; RK,** R. Kramer
Funding: The NIRSE-GAL study (CEIC2023–377, ClinicalTrials.gov number, NCT06180993 is funded by Sanofi/AstraZeneca through a research grant to the Healthcare Research Institute of Santiago

Background and Objective

2023

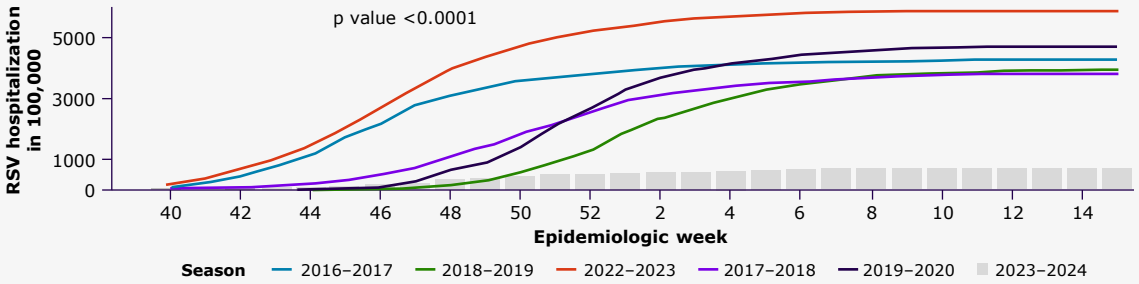
Galicia adopted a universal prophylaxis strategy against RSV in infants with nirsevimab[1]

2024

The **NIRSE-GAL** study reported a substantial reduction in[2]:

- RSV-related LRTI hospitalizations in infants
- Severe RSV-related LRTI hospitalizations with oxygen requirement
- All-cause LRTIs

Cumulative RSV-related LRTI hospitalizations rate (per 100,000) in Galicia, by RSV season[3]



RSV causes a substantial burden in infants, particularly those with underlying conditions. Although most RSV LRTI hospitalisations occur in previously healthy children, infants with comorbidities have a markedly higher risk of severe disease

Infants with comorbidities present with *4x* higher PICU risk, longer hospital stay and higher mortality[4]

Objective: To evaluates the burden and temporal trends of RSV-LRTI hospitalisations among high-risk infants across two consecutive seasons of universal prophylaxis.

CI, confidence interval**; LRTI,** lower respiratory tract infection**; PICU,** Pediatric intensive care unit; **RSV,** respiratory syncytial virus

References: 1. Martinón-Torres F et al (NIRSE-GAL study). Euro Surveill 2023 Dec;28(49):2300606 **2.** Ares S et al (NIRSE-GAL study). Lancet Inf Dis 2024, Aug;24(8):817-828 **3.** Mallah N et al (NIRSE-GAL study). Lancet Inf Dis 2025 Feb;25(2):e62-e63.4. Dallagiacoma G, et al.. Lancet Reg Health Eur. 2025 Sep 9;58:101447.

Study Design

2023

2024

2025

Study Population

All High-risk children <24 months in Galicia offered nirsevimab during two campaigns:

- Season 1: 25 September 2023 – 31 March 2024
- Season 2: 23 September 2024 – 31 March 2025

Re-immunisation allowed if eligibility persisted in 2024/25.

Eligibility criteria

Infants with congenital heart disease, severe immunosuppression, metabolic disorders, neuromuscular diseases, severe pulmonary disease, genetic syndromes with respiratory compromise, trisomy 21, cystic fibrosis, bronchopulmonary dysplasia and prematurity <35 weeks.

Data Collection and Study Outcomes

- Linked electronic hospital and primary-care records (2017–2025) to identify comorbidities, RSV-LRTI hospitalisations, and outpatient visits.

LRTI, lower respiratory tract infection**; RSV,** respiratory syncytial virus

Results

2017-2025

N = 1,097

High-risk children hospitalized for LRTI

N=570

52% Infants with at least one RSV-related admissions

Median age at admission
6.05 months
(IQR 2.30–12.61)

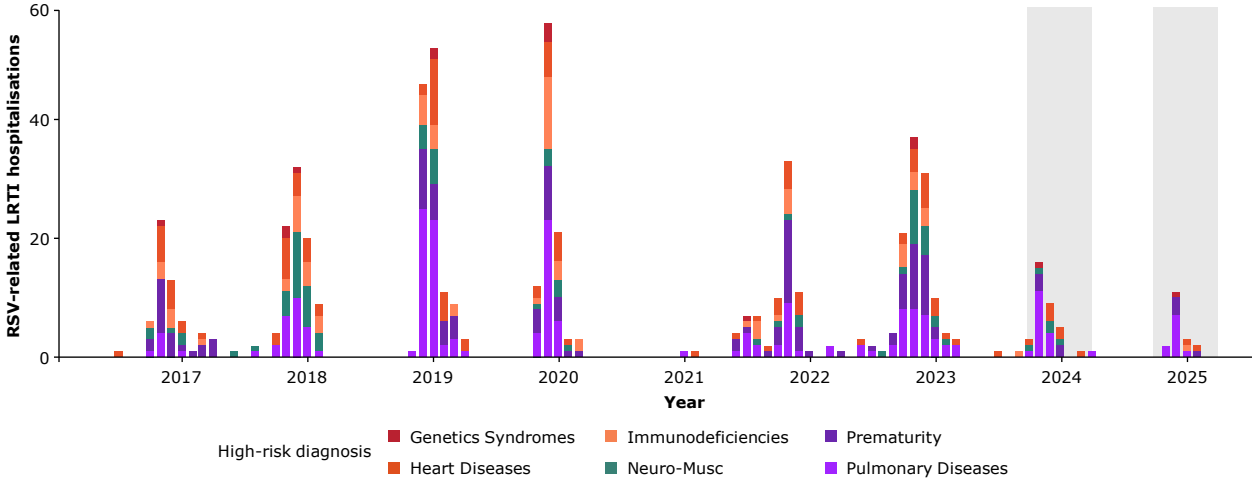
Median length of stay
5 days
(IQR 4–7)

IQR, interquartile range**; LRTI,** lower respiratory tract infection**; RSV,** respiratory syncytial virus

Results

RSV-related lower respiratory tract infection hospitalisations among infants <24 months at high-risk of severe RSV infection by comorbidity category, 2017–2025

Figure 1: Stacked area chart showing annual RSV-LRTI hospitalisations stratified by six comorbidity categories (genetic syndromes, immunodeficiencies, prematurity, congenital heart disease, neuromuscular disorders, and chronic pulmonary disease). Data span the pre-implementation period (2017–2022), universal nirsevimab prophylaxis introduction (September 2023), and two consecutive seasons of implementation (2023/24 and 2024/25).



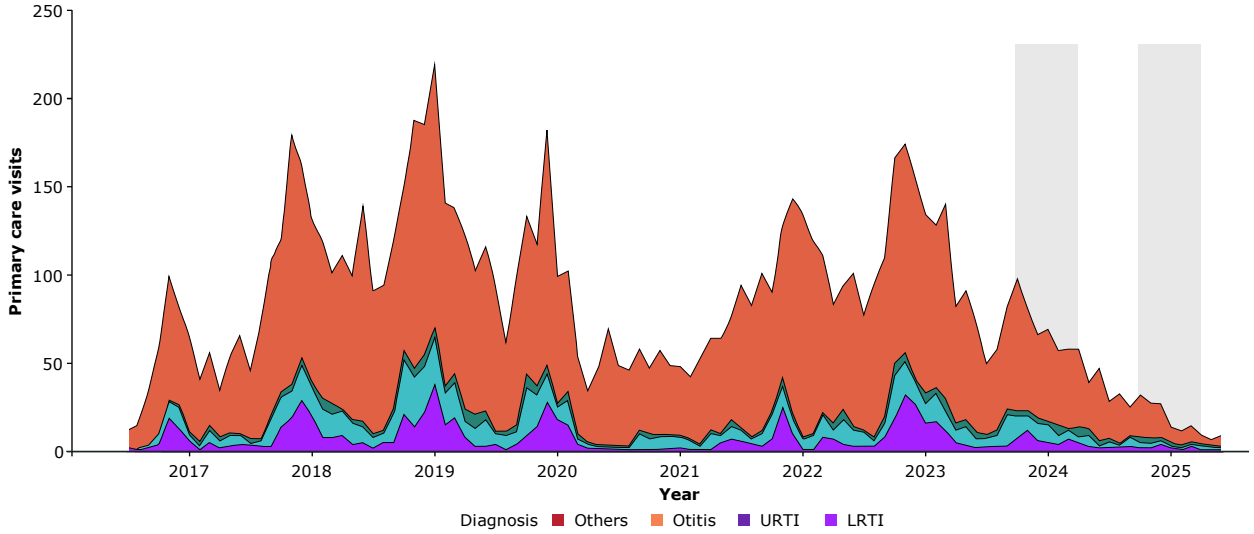
- Chronic pulmonary disease (n=194) and prematurity (n=157) were the most frequent comorbidities (Figure 1)
- Across non-pandemic pre-implementation seasons, RSV-LRTI admission rates ranged from 35.53 to 58.94 per 1,000 (median 49.26/1,000)
- Following nirsevimab implementation, observed rates declined to 29.57/1,000 in 2023/24 and 17.89/1,000 in 2024/25

LRTI, lower respiratory tract infection**; RSV,** respiratory syncytial virus

Results

Primary Care visits by diagnosis among high-risk children with RSV-LRTI hospitalization (2017–2025)

Figure 2: Temporal trends in primary care utilization stratified by diagnosis category (general diagnoses, otitis media, upper respiratory tract infections [URTI], lower respiratory tract infections [LRTI], and other conditions)



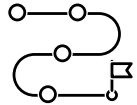
LRTI-related outpatient visits among children with at least one RSV-LRTI hospitalization declined (Figure 2) post-nirsevimab introduction (2023-2024 and 2024-2025)

LRTI, lower respiratory tract infection**; RSV,** respiratory syncytial virus; **URTI,** upper respiratory tract infections

Conclusions

- RSV accounts for approximately half of LRTI hospitalisations among high-risk infants in this population
- Descriptive data across two consecutive seasons of universal nirsevimab prophylaxis show a consistent reduction in RSV-LRTI hospitalisation rates and related primary care visits

Descriptive real-world data across two consecutive seasons supports universal nirsevimab prophylaxis including high-risk infant populations



Future Direction

Formal effectiveness analyses are ongoing to quantify impact beyond inter-seasonal variability

LRTI, lower respiratory tract infection**; RSV,** respiratory syncytial virus; **URTI,** upper respiratory tract infections

Irene Rivero-Calle M.D.
Hospital Clínico Universitario de Santiago de Compostela

Slides QR

Link:
https://www.nirsegal.es/en

Copies of this oral presentation obtained through Quick Response (QR) Code are for personal use only