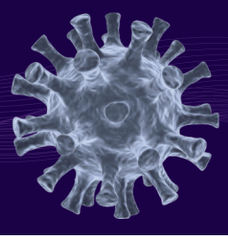
Publication Card

Effectiveness of nirsevimab immunization on invasive pneumococcal disease (IPD) in children nationwide in France



July 2026

Authors: Fafi I*, Valtuille Z*, Kaguelidou F*, Levy C, Cohen R, Angoulvant F, Bizot E, Bonacorsi S, Birgy A, Pontual L, Viriot D, Cohen J, Bourmaud A, Assad Z, Jaboyedoff M, Lenglart L, Boutillier B, Naudin J, Tubiana S, Bezin J, Gras-Le Guen C, Varon E, Basmaci R*, Ouldali N*

Journal: *Lancet Infect Dis*

INTRODUCTION[1]

IPD

Streptococcus pneumoniae remains a leading cause of morbidity and mortality accounting for over 300,000 deaths annually in children younger than 5 years of age worldwide

Role of RSV

Respiratory syncytial virus infection is suspected of facilitating the transition from pneumococcal nasopharyngeal colonization to IPD by increasing bacterial adhesion, impairing mucociliary clearance, and enhancing local inflammation

PCV immunization

Until June 2024, PCV13 was the sole PCV recommended for both primary and booster immunization in France

- KNOWLEDGE GAP No population-based study has assessed whether preventing RSV disease could reduce the incidence of IPD in children
- Nirsevimab is a long-acting monoclonal antibody for the prevention of severe RSV disease in infants[2]
- **Nirsevimab has not been approved or evaluated for protection against IPD by the FDA**
- **Information may not be consistent with the approved product labeling; this information may relate to the indication or use, or other potential unapproved uses.**
- **No conclusions regarding safety and efficacy can be made for such uses**

OBJECTIVE

Assess the effectiveness of nirsevimab immunization in preventing IPD in children

METHODS

Study Information

Study design:
Population-based, national, retrospective cohort study

Location:
France

Nirsevimab campaign dates:
Sept 15, 2023 through Jan 31, 2024

Data:
Included infants: All children born between Feb 6, 2023 and Jan 31, 2024
Data source: French National Health Data System (SNDS) nationwide database (covering approximately 99% of the French population)

Statistical analysis:
Primary analysis relied on a propensity score analysis using inverse probability of treatment weighting (IPTW) method

Outcomes

Primary Endpoint

IPD related hospitalization among immunized vs non-immunized children within 6 months following inclusion

Identified using ICD-10 codes

Secondary Endpoints

- Hospitalization for IPD within 9 months
- Hospitalization for IPD within 6 months according to
  - prematurity (birth <37 vs ≥37 wGA)
  - Birthweight (<2.5kg vs ≥2.5kg)

Population

608,641 children born in France during study period assessed for eligibility

66,844 not included due to being born in maternity units not reporting data on nirsevimab immunization and not receiving immunization in ambulatory settings

13,826 excluded
- 11,656 same-sex twins
- 1,593 immunized with palivizumab
- 328 died before the inclusion date
- 26 hospitalized for IPD before the inclusion date
- 223 died during the study period*

527,971 included in the main analysis

119,435 received nirsevimab

644 lost to follow-up

17 IPD cases occurred

408,536 did not receive nirsevimab

4,031 lost to follow-up

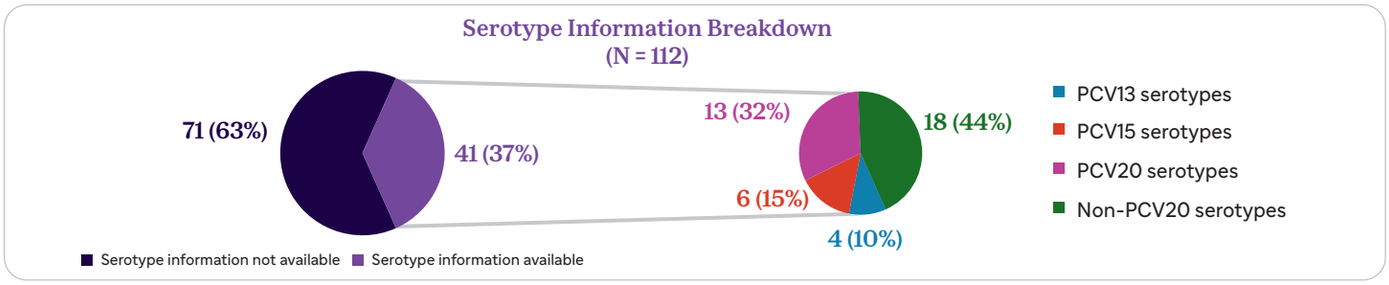
95 IPD cases occurred

sanofi

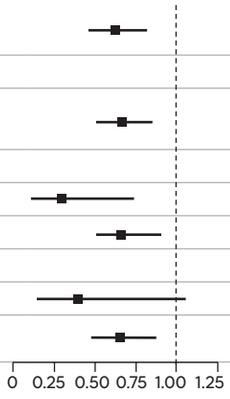
MAT-US-2610559 | V1.0 – Approved 09/ 2026

RESULTS

- 22.6% of the included population received nirsevimab vs 77.4% who did not
- During the 6-month follow-up period, there were ***112 cases of IPD***
  - **Primary Outcome:** Nirsevimab was associated with a 36% reduction in the odds of hospitalization for IPD (OR 0.64, 95% CI 0.46-0.82)
    - 17 cases (14.2 per 100k) in the immunized group vs. 95 (23.3 cases per 100k) in the non-immunized group
  - Results from all sensitivity analyses yielded effectiveness estimates consistent with the main analysis
  - The negative control outcome analysis found no association between nirsevimab immunization and invasive group B streptococcal disease
- Among the ***112 cases of IPD***
  - 72 (64%) were bacteremic pneumococcal pneumonia or pneumococcal pneumonia with pleural effusion, 20 (18%) were meningitis, 11 (10%) were bacteremia without source, 9 (8%) were other infections
  - 36 (32%) required ICU care, 47 (42%) required mechanical ventilation
  - 6 (5%) cases resulted in death, all in the non-immunized group
- Pneumococcal serotypes were available for 41 (37%) of 112 IPD cases



	Immunized with nirsevimab* N = 119,435	Not immunized with nirsevimab* N = 408,536	Adjusted OR (95% CI)
Hospitalization for IPD within 6 months of inclusion (primary analysis)	17 (14.2/100,000)	95 (23.3/100,000)	0.64 (0.46–0.82)
Secondary analyses			
Hospitalization for IPD within 9 months of inclusion	23 (19.3/100,000)	113 (27.7/100,000)	0.66 (0.51–0.85)
Weight groups			
Birthweight <2.5kg	2/8,140 (24.6/100,000)	15/22,836 (65.7/100,000)	0.29 (0.11–0.74)
Birthweight ≥2.5kg	15/111,295 (13.5/100,000)	80/385,700 (20.7/100,000)	0.66 (0.51–0.90)
Gestational age, weeks			
<37 (preterm birth) (n/N)	2/7,573 (26.4/100,000)	10/20,227 (49.4/100,000)	0.39 (0.14–1.06)
≥37 (term birth) (n/N)	15/111,862 (13.4/100,000)	85/388,309 (21.9/100,000)	0.65 (0.48–0.87)



On the graph, circles indicate point estimates and horizontal lines indicate 95% CIs. All analyses were performed using a logistic regression model.
All analyses excluded six patients, for whom the French Social Deprivation Index was missing. *Crude incidence

Strengths

- Large, nationwide sample size
- Several sensitivity analyses were performed to assess the robustness of the findings

Limitations

- ICD-10 codes might introduce misclassifications of IPD cases
- Nirsevimab shortage may have led to differential uptake, introducing bias
- Residual bias related to differential weighting of children could not be excluded due to the allowance of varied ratio of immunized to non-immunized matching
- Almost all children had received PCV13 (>90% national coverage), with slightly higher in the nirsevimab immunized group
- Children who were lost to follow-up were considered free of disease in the main analysis, which might have introduced bias

KEY MESSAGES

1. Growing body of evidence suggests an interaction between with RSV and *S pneumoniae*. This study adds new quasi-experimental evidence in support of a key role for RSV in inducing IPD.
2. Nirsevimab immunization in children younger than 12 months of age was associated with lower risk of IPD at 6 months following immunization. This association remained at 9 months of follow-up.

Abbreviation: CI, confidence interval; FDA, Food & Drug Administration; ICD-10, International Classification of Diseases, Tenth Revision; OR, odds ratio; PCV, pneumococcal conjugate vaccine; wGA, weeks gestational age.

References: 1. Fafi I, Valtuille Z, Kaguelidou F, et al. Effectiveness of nirsevimab immunization on invasive pneumococcal disease in children nationwide in France: an observational cohort study. Lancet Infect Disease.2026;S1473-3099(26)00253-7. **2.** Beyfortus [Package Insert]. Swiftwater, PA: Sanofi; June 2026.

For use by Sanofi medical affairs for scientific exchange and medical discussions only. do not photograph, copy or distribute.

sanofi

©2026 Sanofi. All rights reserved.

Access the publication

MAT-US-2610559 | V1.0 – Approved 09/ 2026