KJM KANSAS JOURNAL OF MEDICINE

Comparative Analysis of Reported Adverse Events with Nirsevimab and Palivizumab in the FAERS Database

Ibrahim Touffaha, MS-3[1]
Elizabeth Ablah, Ph.D.[1,2]
Hayrettin Okut, Ph.D.[1,2]
Gretchen Homan, M.D.[1,3]
[1] University of Kansas School of Medicine, Wichita, Kansas
[2] Department of Population Health
[3] Department of Pediatrics

Received April 2, 2026; Accepted for publication July 13, 2026; Published online August 18, 2026, Kans J Med 2026 Jul-Aug; 19:76-83. https://doi.org/10.17161/kjm.vol19.25544.

Conflict of Interest Disclosure: *None.*

Corresponding Author:
Ibrahim Touffaha, MS-3
The University of Kansas School of Medicine-Wichita
1010 N. Kansas St., Wichita, KS 67214
itouffaha@kumc.edu

ABSTRACT

Introduction. Respiratory syncytial virus (RSV) remains a leading cause of hospitalization among infants. Palivizumab has long been used for RSV prophylaxis in high-risk infants, whereas nirsevimab is a newer long-acting monoclonal antibody approved for broader use. Although clinical trials have demonstrated comparable safety profiles, comparative post-marketing safety data remain limited. Authors of this study compared reported adverse events associated with palivizumab and nirsevimab using the FDA Adverse Event Reporting System (FAERS).

Methods. A retrospective cross-sectional pharmacovigilance study was conducted using FAERS reports. Adverse events were classified according to the Medical Dictionary for Regulatory Activities (MedDRA) System Organ Classes. Comparative analyses were performed using chi-square tests and binary logistic regression, with palivizumab as the reference group. Odds ratios (ORs) and 95% confidence intervals (CIs) were reported.

Results. A total of 2,021 reports met the inclusion criteria, including 1,380 for palivizumab and 641 for nirsevimab. Compared with palivizumab reports, nirsevimab reports had higher odds of including injury, poisoning, and procedural complications (OR, 7.55; 95% CI, 5.57–10.35) and skin and subcutaneous tissue disorders (OR, 2.55; 95% CI, 1.51–4.33). Nirsevimab reports had lower odds of including infections and infestations (OR, 0.51; 95% CI, 0.40–0.65), gastrointestinal disorders (OR, 0.29; 95% CI, 0.15–0.52), investigations (OR, 0.37; 95% CI, 0.18–0.68), and respiratory, thoracic, and mediastinal disorders (OR, 0.64; 95% CI, 0.51–0.80).

Conclusions. Nirsevimab and palivizumab demonstrated distinct post-marketing adverse event reporting patterns. Continued post-marketing surveillance is warranted to further characterize the safety profiles of both agents.

INTRODUCTION

Respiratory syncytial virus (RSV) is a leading cause of acute lower respiratory tract infections among infants worldwide.[1] In 2019, an estimated 1.4 million RSV-associated hospital admissions occurred among infants aged 0-6 months, resulting in approximately 13,300 in-hospital deaths globally.[1] In the United States, RSV is highly prevalent among infants, with 53.4% of healthy term infants infected during their first year of life.[2] Although most infections are mild, RSV remains a leading cause of pediatric hospitalization, with a hospitalization rate of 8.5 per 1,000 infants aged 0-7 months during the 2024-2025 RSV season.[3]

Management of RSV infection primarily is supportive and includes respiratory support when needed. Additional therapies include ribavirin, monoclonal antibodies, glucocorticoids, and bronchodilators.[4] Ribavirin, a nucleoside analog that inhibits both DNA and RNA virus replication, is expensive and teratogenic, limiting its use primarily to selected immunocompromised patients. Monoclonal antibodies, including palivizumab and motavizumab, have not demonstrated significant reductions in hospital length of stay.[5,6] Likewise, glucocorticoids and bronchodilators have not been shown to improve the clinical course of hospitalized infants and children[7] or reduce hospitalization rates or duration for respiratory viral infections.[8] Consequently, preventing RSV through vaccination and passive immunization has become a major public health priority.

Palivizumab, the first passive immunization approved by the United States Food and Drug Administration (FDA) for RSV prevention, is a humanized monoclonal antibody that targets the RSV fusion (F) protein, preventing viral entry into respiratory epithelial cells.[9] Although it is not effective for treating active RSV infection, monthly intramuscular administration reduces RSV-related hospitalizations by approximately 56% among high-risk infants.[10] Nirsevimab is a recombinant human monoclonal antibody that binds the prefusion RSV F protein and likewise prevents viral entry into respiratory epithelial cells.[11] Unlike palivizumab, nirsevimab provides season-long protection with a single dose and has been shown to reduce RSV-associated hospitalizations by 78%.[12] Clinical trials have demonstrated comparable safety profiles for palivizumab and nirsevimab.[13]

Despite favorable clinical trial findings, post-marketing surveillance remains essential for detecting rare or serious adverse events that may not be identified during pre-approval studies. To our knowledge, no published study has directly compared post-marketing adverse event reports for nirsevimab and palivizumab. Given the increasing use of nirsevimab and the historical role of palivizumab in RSV prophylaxis, understanding differences in their post-marketing safety profiles is important for informing clinical practice and ensuring patient safety. Although palivizumab was discontinued on December 31, 2025, after more than two decades of clinical use, it remains an important comparator for evaluating the safety of newer long-acting monoclonal antibodies. Therefore, we compared adverse event reports associated with nirsevimab and palivizumab using the FDA Adverse Event Reporting System (FAERS).

METHODS

Participants

The United States FDA FAERS is a publicly available pharmacovigilance database used for post-marketing surveillance of pharmaceuticals and biologic products.[14] It contains voluntary reports of adverse events and medication errors submitted by health care professionals, consumers, and manufacturers. The analysis included reports submitted from July 2023, when nirsevimab received FDA approval, through March 2025, the most recent data available at the time of analysis. Reports were eligible if patients were ≤2 years of age and either nirsevimab or palivizumab was listed as the primary suspect drug. Reports with missing information required to determine eligibility or drug exposure (e.g., drug name or adverse event details) were excluded. Duplicate reports identified by matching case numbers were also excluded.

Instruments

Data extracted from FAERS included patient demographics (age, sex, and country of origin), reporter type (healthcare professional or consumer), drug characteristics (route of administration, dose, dosage form, dosing frequency, cumulative dose before the adverse event, and indication for use), reported adverse events, and patient outcomes (hospitalization, disability, life-threatening event, death, and other medically important conditions).

Adverse events were coded using the MedDRA, an internationally standardized medical terminology for regulatory reporting of medical products.[14] MedDRA classifies adverse

events using a hierarchical structure consisting of System Organ Classes (SOCs), High-Level Group Terms, High-Level Terms (HLTs), Preferred Terms (PTs), and Lowest Level Terms.

Procedures

The study was approved by the University of Kansas Medical Center Institutional Review Board (IRB). FAERS data from the third quarter of 2023 through the first quarter of 2025 were extracted and deduplicated according to FDA recommendations and published methods.[15,16] When multiple reports shared the same CASEID, the report with the most recent FDA_DT (FDA receipt date) was retained. If both the CASEID and FDA_DT were identical, the report with the higher PRIMARYID was retained. This approach ensured inclusion of the most complete and up-to-date version of each adverse event report. Both generic and brand names – palivizumab (Synagis®) and nirsevimab (Beyfortus®) – were used to identify eligible reports.

Following data extraction and deduplication, adverse events were coded using MedDRA Preferred Terms and subsequently grouped into their corresponding SOCs for analysis.

Statistical Analysis

All analyses were performed using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA). Data preparation included applying the eligibility criteria, removing duplicate reports, addressing missing or inconsistent data, calculating time to adverse event onset when available, and classifying adverse events according to MedDRA.

Continuous variables (e.g., age) were summarized using means, standard deviations, medians, interquartile ranges, minima, and maxima. Categorical variables (e.g., sex, reported drug, adverse event categories, and patient outcomes) were summarized using frequencies and percentages.

Baseline characteristics were compared between palivizumab and nirsevimab reports using chi-square or Fisher's exact tests for categorical variables and Student's *t*-tests or Mann-Whitney *U* tests for continuous variables, as appropriate.

To compare adverse event reporting across SOCs, separate binary logistic regression models were fitted for each SOC. The dependent variable was the presence or absence of at least one adverse event within the SOC, and the independent variable was drug exposure (nirsevimab versus palivizumab), with palivizumab serving as the reference group. Odds ratios (ORs), 95% confidence intervals (CIs), and p values were reported.

All statistical tests were two-sided, and statistical significance was defined as $p < 0.05$. Because the SOC-specific analyses were exploratory and hypothesis-generating, no adjustment was made for multiple comparisons. Findings were interpreted based on the magnitude and precision of the estimated ORs and their 95% CIs rather than statistical significance alone. The study was reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.[17]

RESULTS

A total of 1,389 reports involving palivizumab (Synagis) and 670 reports involving nirsevimab (Beyfortus) were identified from the FAERS database. After applying inclusion and exclusion criteria, 38 reports were excluded due to age >2 years. The final analytic sample included 2,021 reports: 1,380 for palivizumab and 641 for nirsevimab.

Report Characteristics

Among palivizumab reports, 56.3% (n = 753; Table 1) were male. The mean age at the time of the adverse event was 6.88 months. The most frequently reported outcomes were hospitalization (69.8%, n = 713), other serious outcomes (18.1%, n = 185), and death (9.8%, n = 100). The most common indication for palivizumab use was prematurity (29.6%, n = 407).

Among nirsevimab reports, 55.6% (n = 223) were male, and the mean age at the time of the adverse event was 3.21 months. The most frequently reported outcomes were hospitalization (50.1%, n = 216), other serious outcomes (36.8%, n = 156), and death (5.9%, n = 25). The most common indication was respiratory syncytial virus immunization (34.2%, n = 145).

Preferred Terms were categorized into SOCs, and results are summarized in Table 2. Binary logistic regression demonstrated higher reporting odds among nirsevimab reports for injury, poisoning, and procedural complications (OR, 7.55; 95% CI, 5.57-10.36, $p < 0.0001$) and skin and subcutaneous tissue disorders (OR, 2.55; 95% CI, 1.51-4.33, $p < 0.001$).

Table 1. Characteristics of FAERS reports for palivizumab vs. nirsevimab.

Characteristic	Palivizumab	Nirsevimab	*t* or $\chi^2(df)$	*P*-value
Age, months	6.88 ± 5.26	3.21 ± 3.64	t = -16.4	<0.0001
Sex, n (%)			$\chi^2(1) = 0.00$	0.9000
Male	753 (56.3)	223 (55.6)		
Female	584 (43.7)	174 (43.4)		
*Missing**	43	244		
Mean weight (kg)	6.49 ± 2.60	5.25 ± 2.20	t = -8.16	<0.0001
Reporter type, n (%)			$\chi^2(3) = 946.40$	<0.0001
Health professional**	309 (22.4)	60 (12.7)		
Medical doctor	123 (8.9)	364 (76.8)		
Consumer	939 (68.1)	25 (5.3)		
Pharmacist	8 (0.6)	25 (5.3)		
*Missing**	1	167		
Serious outcomes, n (%)			$\chi^2(6) = 88.67$	<0.0001
Hospitalization	713 (69.8)	216 (50.1)		
Other serious outcomes	185 (18.1)	156 (36.8)		
Death	100 (9.8)	25 (5.9)		
Life-threatening events	19 (1.9)	18 (4.3)		
Disability	1 (0.1)	4 (0.9)		
Congenital anomaly	3 (0.3)	1 (0.24)		
Required intervention to prevent permanent damage	0 (0.0)	4 (0.94)		
*Missing**	362	222		
Top indications, n (%)			$\chi^2(111) = 1067.36$	<0.0001
Premature baby	407 (29.6)	1 (0.2)		
Antiviral prophylaxis	291 (21.2)	111 (26.2)		
RSV immunization	12 (1.0)	145 (34.2)		
Immunization	2 (0.2)	99 (23.4)		
Unknown indication	190 (12.8)	12 (2.4)		

*Percentages were calculated using reports with non-missing data for each variable. Missing values are presented as counts and were excluded from percentage calculations and statistical comparisons.
**Health professionals included nurses, physician assistants, and other healthcare workers other than physicians.

In contrast, nirsevimab was associated with lower reporting odds for infections and infestations (OR, 0.51; 95% CI, 0.40-0.65, p <0.0001), gastrointestinal disorders (OR, 0.29; 95% CI, 0.15-0.52, p <0.0001), investigations (OR, 0.37; 95% CI, 0.18-0.68, p = 0.0027), and respiratory, thoracic, and mediastinal disorders (OR, 0.64; 95% CI, 0.51-0.80, p <0.001), indicating relatively higher reporting among palivizumab cases.

To further explore SOC-level differences, we examined the distribution of corresponding HLTs within these categories. Table 3 summarizes the most frequently reported HLTs and highlights specific event types contributing to the observed SOC-level differences.

DISCUSSION

Post-marketing surveillance plays an essential role in evaluating drug safety in real-world clinical settings, particularly following the introduction of newly approved therapies. Early post-marketing periods often are characterized by increased adverse event reporting due to expanded clinical adoption, heightened awareness, and increased reporting vigilance among healthcare professionals. Similar patterns have been documented during the early rollout of nirsevimab in Spain, where implementation was associated with increased reporting as utilization expanded.[18] These findings highlight the importance of continued pharmacovigilance during the early adoption phase of novel immunoprophylactic agents, when reporting patterns may reflect both clinical experience and system-level implementation effects.

Demographic and Clinical Characteristics

In this analysis, palivizumab reports involved a slightly

Table 2. Comparison of adverse events by system organ class between palivizumab and nirsevimab, FAERS 2023–2025.

System Organ Class	Palivizumab	Nirsevimab	Odds Ratio (95% CI)
Blood and lymphatic system disorders	8 (0.6%)	3 (0.5%)	0.81 (0.18–2.80)
Cardiac disorders	31 (2.3%)	8 (1.3%)	0.55 (0.23–1.15)
Congenital, familial and genetic disorders	3 (0.2%)	2 (0.3%)	1.44 (0.19–8.69)
Ear and labyrinth disorders	1 (0.1%)	0 (0%)	N/A
Eye disorders	5 (0.4%)	5 (0.8%)	2.16 (0.60–7.80)
Gastrointestinal disorders	84 (6.1%)	12 (1.9%)	0.29 (0.15-0.52)
General disorders and administration site conditions	251 (18.2%)	124 (19.3%)	1.08 (0.85–1.37)
Hepatobiliary disorders	3 (0.2%)	0 (0%)	N/A
Immune system disorders	6 (0.4%)	3 (0.5%)	1.08 (0.23–4.10)
Infections and infestations	337 (24.4%)	91 (14.2%)	0.51 (0.40-0.65)
Injury, poisoning and procedural complications	62 (4.5%)	168 (26.2%)	7.55 (5.57-10.35)
Investigations	62 (4.5%)	11 (1.7%)	0.37 (0.18-0.68)
Metabolism and nutrition disorders	26 (1.9%)	9 (1.4%)	0.74 (0.32-1.53)
Musculoskeletal and connective tissue disorders	6 (0.4%)	1 (0.2%)	0.36 (0.01-2.1)
Neoplasms benign, malignant and unspecified	2 (0.1%)	2 (0.3%)	2.15 (0.25-18.0)
Nervous system disorders	31 (2.3%)	23 (3.6%)	1.62 (0.93–2.79)
Pregnancy, puerperium and perinatal conditions	1 (0.1%)	1 (0.2%)	2.15 (0.09–54.55)
Psychiatric disorders	12 (1.0%)	2 (0.3%)	0.33 (0.05–1.20)
Renal and urinary disorders	5 (0.36%)	1 (0.2%)	0.43 (0.02–2.67)
Reproductive system and breast disorders	1 (0.1%)	0 (0%)	N/A
Respiratory, thoracic and mediastinal disorders	387 (28.0%)	128 (20.0%)	0.64 (0.51–0.80)
Skin and subcutaneous tissue disorders	27 (2.0%)	31 (4.8%)	2.55 (1.51–4.33)
Social circumstances	1 (0.1%)	2 (0.3%)	4.32 (0.41–92.98)
Surgical and medical procedures	7 (0.5%)	4 (0.62%)	1.23 (0.32–4.09)
Vascular disorders	20 (1.5%)	10 (1.6%)	1.08 (0.48–2.26)

Note: OR, Odds Ratio (palivizumab was the reference); CI, Confidence Interval.

higher proportion of male patients (56.3%), consistent with prior literature, including Chen et al.,[19] which also reported male predominance among RSV prophylaxis recipients. The mean age of reported cases was 6.9 months. In contrast, nirsevimab reports showed a similar male predominance (55.6%) but a younger mean age of 3.21 months, consistent with Spanish pharmacovigilance data reporting a comparable age distribution and male predominance.[18] These similarities suggest consistency in demographic reporting patterns across settings.

Differences in reported serious outcomes were observed between the two drugs. Hospitalization and death were more frequently reported in palivizumab cases, whereas life-threatening events and other serious outcomes were proportionally more common in nirsevimab reports. However, these differences should be interpreted cautiously. Palivizumab is primarily used in high-risk infants, including those born prematurely or with underlying cardiopulmonary disease, whereas nirsevimab is administered to a broader infant population, including otherwise healthy infants. Therefore, differences in baseline clinical risk, indication, and reporting sources likely contribute to observed outcome differences rather than true differences in safety profiles.

System Organ Class Findings

At the SOC level, palivizumab reports most frequently involved respiratory, thoracic, and mediastinal disorders (28.0%), infections and infestations (24.4%), and general disorders and administration site conditions (18.2%). These findings are consistent with known clinical trial data, which report fever, respiratory infections, and injection-site reactions as common adverse events.[20] Rare hypersensitivity reactions were infrequently reported, consistent with previous studies.[20]

For nirsevimab, the most frequently reported SOCs included injury, poisoning, and procedural complications (26.2%), respiratory disorders (20.0%), and general disor-

Table 3. Most frequently reported high-level terms within significant system organ classes.

System Organ Class/ High-Level Term	Palivizumab	Nirsevimab
Skin and subcutaneous tissue disorders		
Rashes, eruptions, and exanthems NEC	0.4% (n = 6)	1.7% (n = 11)
Urticarias	0.0% (n = 0)	0.9% (n = 6)
Infections and infestations		
Respiratory syncytial viral infections	5.4% (n = 74)	12.0% (n = 77)
Upper respiratory tract infections	3.7% (n = 51)	0.2% (n = 1)
Lower respiratory tract and lung infections	3.1% (n = 43)	0.5% (n = 3)
Influenza viral infections	2.5% (n = 35)	0.2% (n = 1)
Coronavirus infections	2.5% (n = 35)	0.3% (n = 2)
Gastrointestinal disorders		
Nausea and vomiting symptoms	0.4% (n = 6)	0.3% (n = 2)
Diarrhea (excluding infective)	0.4% (n = 6)	0.0% (n = 0)
Gastrointestinal signs and symptoms NEC	0.2% (n = 3)	0.0% (n = 0)
Investigations		
Blood gas and acid-base analyses	0.4% (n = 6)	0.2% (n = 1)
Physical examination procedures and organ system status	0.3% (n = 4)	0.0% (n = 0)
Respiratory, thoracic, and mediastinal disorders		
Bronchial conditions NEC	7.0% (n = 96)	11.2% (n = 72)
Coughing and associated symptoms	7.8% (n = 108)	2.2% (n = 14)
Breathing abnormalities	5.0% (n = 69)	2.7% (n = 17)
Injury, poisoning, and procedural complications		
Product administration errors and issues	1.6% (n = 22)	18.0% (n = 115)
Product storage errors and issues in the product use system	0.0% (n = 0)	3.3% (n = 21)
Medication/product use errors and issues NEC	0.1% (n = 2)	1.6% (n = 10)

Note: NEC, Not elsewhere classified.

ders and administration site conditions (19.3%). The injury, poisoning, and procedural complications category was largely driven by administration errors, product storage issues, and medication use errors. These findings likely reflect real-world implementation challenges associated with early adoption of a newly introduced product rather than pharmacologic toxicity. Similar patterns were observed during early national rollout in Spain.[18]

Respiratory-related events included both therapeutic and non-therapeutic responses and were broadly consistent with clinical trial findings, including injection-site reactions and rash, which were reported as uncommon adverse events.[21] A subset of nirsevimab reports included RSV infection (12.0%), which may represent breakthrough infections; however, FAERS data cannot confirm infection status, causality, or prophylactic effectiveness due to the absence of denominators and detailed clinical information.[22]

Comparative Adverse Event Patterns

Comparative analysis demonstrated differences across several SOCs, including infections and infestations, respiratory disorders, gastrointestinal disorders, investigations, skin disorders, and injury, poisoning, and procedural complications.

Infections and infestations were more frequently reported in palivizumab cases (24.4%) compared with nirsevimab (14.2%). However, RSV infection specifically was more frequently reported in nirsevimab cases (12.0% vs 5.4%). This discrepancy may reflect several factors, including misclassification (e.g., prophylaxis indication recorded as an adverse event), breakthrough infection reporting, or differences in coding practices. FAERS does not allow determination of true infection rates or comparative effectiveness. Additionally, higher infection-related reporting in the palivizumab group may reflect its use in higher-risk infants with prematurity or cardiopulmonary disease, who are inherently more susceptible to infection. These baseline differences limit direct comparison and support a descriptive, hypoth-

esis-generating interpretation.

A marked difference was observed in injury, poisoning, and procedural complications, which were substantially higher in nirsevimab reports (26.2% vs 4.5%). This category was predominantly driven by administration and handling errors. These findings are likely to reflect implementation challenges associated with a newly introduced product. In contrast, palivizumab has been in clinical use for over two decades with well-established administration protocols. Increased reporting among healthcare professionals for nirsevimab also may reflect heightened vigilance related to a newly approved therapy. Overall, these findings likely represent system-level implementation issues rather than intrinsic drug toxicity and may decrease as clinical familiarity increases.

Respiratory, thoracic, and mediastinal disorders were more frequently reported with palivizumab (28.0% vs 20.0%), largely driven by cough and respiratory symptoms. Bronchial conditions not elsewhere classified were more frequently reported with nirsevimab. However, FAERS data do not permit determination of whether these differences reflect true clinical variation, differences in patient populations, or reporting behavior.

Gastrointestinal disorders and investigations also were more frequently reported in palivizumab cases. Although statistically significant, these differences were based on relatively small event counts and should be interpreted cautiously. They may reflect differences in baseline clinical complexity rather than drug-related effects.

Skin and subcutaneous tissue disorders were more frequently reported with nirsevimab, primarily driven by rash and urticaria. This may suggest differences in hypersensitivity reporting patterns between agents; however, low absolute event counts limit definitive interpretation.

Limitations

This study has several limitations inherent to FAERS. As a passive surveillance system, FAERS is subject to underreporting, reporting bias, and variability in data completeness. Reporter type differed between groups, with palivizumab reports more frequently submitted by consumers and nirsevimab reports more frequently submitted by healthcare professionals. This imbalance may influence observed reporting patterns, as healthcare professionals are more likely to report administration or handling errors, whereas consumers may be more likely to report symptoms.

In addition, differences in age, indication, and baseline clinical risk limit direct comparability between groups. Observed differences in serious outcomes likely reflect underlying patient characteristics and reporting behavior rather than true differences in safety profiles. Finally, increased reporting following nirsevimab approval may reflect heightened awareness and reporting intensity rather than true differences in adverse event frequency.

CONCLUSIONS

Nirsevimab and palivizumab demonstrated distinct post-marketing adverse event reporting patterns in FAERS. Higher reporting of procedural and administration-related events with nirsevimab likely reflects early implementation challenges, whereas higher reporting of infectious and respiratory events with palivizumab likely reflects differences in underlying patient populations. Continued pharmacovigilance is warranted to further characterize the real-world safety profiles of these agents.

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Keywords: *respiratory syncytial virus; palivizumab; nirsevimab; pharmacovigilance; drug-related side effects and adverse reactions*